

TG THERAPEUTICS, INC.
Form 10-Q
August 09, 2018

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended June 30, 2018

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

Commission File Number 000-30929

TG THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware 36-3898269
(State or other jurisdiction of incorporation or organization) (I.R.S. Employer Identification No.)

2 Gansevoort Street, 9th Floor
New York, New York 10014
(Address including zip code of principal executive offices)

(212) 554-4484
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes No

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Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See definition of “large accelerated filer,” “accelerated filer,” “smaller reporting company,” and “emerging growth company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer (Do not check if smaller reporting company) Smaller reporting company

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by checkmark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes No

There were 82,818,608 shares of the registrant’s common stock, \$0.001 par value, outstanding as of August 3, 2018.

TG THERAPEUTICS, INC.
FORM 10-Q
FOR THE QUARTER ENDED JUNE 30, 2018

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SPECIAL CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

Certain matters discussed in this report, including matters discussed under the caption “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” may constitute forward-looking statements for purposes of the Securities Act of 1933, as amended, or the Securities Act, and the Securities Exchange Act of 1934, as amended, or the Exchange Act, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from the future results, performance or achievements expressed or implied by such forward-looking statements. The words "anticipate," "believe," "estimate," "may," "expect," "plan," "intend" and similar expressions are generally intended to identify forward-looking statements. Our actual results may differ materially from the results anticipated in these forward-looking statements due to a variety of factors, including, without limitation, those discussed under the captions “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this report, as well as other factors which may be identified from time to time in our other filings with the Securities and Exchange Commission, or the SEC, or in the documents where such forward-looking statements appear. All written or oral forward-looking statements attributable to us are expressly qualified in their entirety by these cautionary statements. Such forward-looking statements include, but are not limited to, statements about our:

expectations for increases or decreases in expenses;

expectations for the clinical and pre-clinical development, manufacturing, regulatory approval, and commercialization of our pharmaceutical product candidates or any other products we may acquire or in-license;

use of clinical research centers and other contractors;

expectations as to the timing of commencing or completing pre-clinical and clinical trials and the expected outcomes of those trials;

expectations for incurring capital expenditures to expand our research and development and manufacturing capabilities;

expectations for generating revenue or becoming profitable on a sustained basis;

expectations or ability to enter into marketing and other partnership agreements;

expectations or ability to enter into product acquisition and in-licensing transactions;

expectations or ability to build our own commercial infrastructure to manufacture, market and sell our drug candidates;

expectations for the acceptance of our products by doctors, patients or payors;

ability to compete against other companies and research institutions;

ability to secure adequate protection for our intellectual property;

ability to attract and retain key personnel;

ability to obtain reimbursement for our products;

estimates of the sufficiency of our existing cash and cash equivalents and investments to finance our operating requirements, including expectations regarding the value and liquidity of our investments;

stock price volatility; and

expectations for future capital requirements.

The forward-looking statements contained in this report reflect our views and assumptions only as of the date this report is signed. Except as required by law, we assume no responsibility for updating any forward-looking statements.

We qualify all of our forward-looking statements by these cautionary statements. In addition, with respect to all of our forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

TG Therapeutics, Inc.
 Condensed Consolidated Balance Sheets
 (in thousands, except share and per share amounts)

	June 30, 2018	December 31, 2017
	(Unaudited)	(Note 1)
Assets		
Current assets:		
Cash and cash equivalents	\$105,672	\$56,718
Short-term investment securities	20,573	27,999
Interest receivable	87	108
Prepaid research and development	8,890	8,056
Other current assets	816	437
Total current assets	136,038	93,318
Restricted cash	1,237	587
Leasehold interest, net	2,376	2,429
Equipment, net	265	248
Goodwill	799	799
Total assets	\$140,715	\$97,381
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	\$35,394	\$25,877
Accrued compensation	1,182	1,800
Current portion of deferred revenue	152	152
Notes payable	210	128
Total current liabilities	36,938	27,957
Deferred rent	1,411	1,364
Deferred revenue, net of current portion	990	1,067
Total liabilities	39,339	30,388
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value per share (10,000,000 shares authorized, none issued and outstanding as of June 30, 2018 and December 31, 2017)	--	--

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Common stock, \$0.001 par value per share (150,000,000 shares authorized, 82,539,417 and 73,181,750 shares issued, 82,498,108 and 73,140,441 shares outstanding at June 30, 2018 and December 31, 2017, respectively)	82	73
Additional paid-in capital	542,062	422,017
Treasury stock, at cost, 41,309 shares at June 30, 2018 and December 31, 2017	(234)	(234)
Accumulated deficit	(440,534)	(354,863)
Total stockholders' equity	101,376	66,993
Total liabilities and stockholders' equity	\$140,715	\$97,381

The accompanying notes are an integral part of the condensed consolidated financial statements.

TG Therapeutics, Inc.
Condensed Consolidated Statements of Operations
(in thousands, except share and per share amounts)
(Unaudited)

	Three months ended June 30,		Six months ended June 30,	
	2018	2017	2018	2017
License revenue	\$38	\$38	\$76	\$76
Costs and expenses:				
Research and development:				
Non-cash stock expense associated with in-licensing agreements	3,000	-	4,000	-
Noncash compensation	888	1,266	3,747	3,573
Other research and development	34,812	25,440	65,971	45,815
Total research and development	38,700	26,706	73,718	49,388
General and administrative:				
Noncash compensation	3,375	223	7,854	3,913
Other general and administrative	2,308	1,534	4,426	2,867
Total general and administrative	5,683	1,757	12,280	6,780
Total costs and expenses	44,383	28,463	85,998	56,168
Operating loss	(44,345)	(28,425)	(85,922)	(56,092)
Other (income) expense:				
Interest income	(189)	(50)	(333)	(95)
Other (income) expense	(14)	(22)	82	84
Total other income, net	(203)	(72)	(251)	(11)
Net loss	\$(44,142)	\$(28,353)	\$(85,671)	\$(56,081)
Basic and diluted net loss per common share	\$(0.59)	\$(0.45)	\$(1.18)	\$(0.96)
Weighted average shares used in computing basic and diluted net loss per common share	74,256,348	63,288,269	72,456,657	58,251,045

The accompanying notes are an integral part of the condensed consolidated financial statements.

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TG Therapeutics, Inc.
Condensed Consolidated Statement of Stockholders' Equity
(in thousands, except share amounts)
(Unaudited)

	Common Stock			Treasury Stock			Total
	Shares	Amount	Additional paid-in capital	Shares	Amount	Accumulated Deficit	
Balance at January 1, 2018	73,181,750	\$73	\$422,017	41,309	\$(234)	\$(354,863)	\$66,993
Issuance of restricted stock	1,420,511	1	(1)	--	--	--	--
Forfeiture of restricted stock	(130,661)	*	*	--	--	--	--
Issuance of common stock in At-the-Market offerings (net of offering costs of \$1.9 million)	7,733,949	8	104,445	--	--	--	104,453
Compensation in respect of restricted stock granted to employees, directors and consultants	--	--	11,601	--	--	--	11,601
Shares issued in connection with in-licensing agreements	333,868	*	4,000	--	--	--	4,000
Net loss	--	--	--	--	--	(85,671)	(85,671)
Balance at June 30, 2018	82,539,417	\$82	\$542,062	41,309	\$(234)	\$(440,534)	\$101,376

* Amount less than one thousand dollars.

The accompanying notes are an integral part of the condensed consolidated financial statements.

TG Therapeutics, Inc.
Condensed Consolidated Statements of Cash Flows
(in thousands)
(Unaudited)

	Six months ended June 30,	
	2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$(85,671)	\$(56,081)
Adjustments to reconcile net loss to net cash used in operating activities:		
Noncash stock compensation expense	11,601	7,485
Noncash licensing expense	4,000	--
Depreciation	41	41
Amortization of premium on investment securities	(9)	45
Change in fair value of notes payable	82	84
Changes in assets and liabilities:		
Increase in other current assets	(1,213)	(4,252)
Decrease in leasehold interest	53	75
Decrease in accrued interest receivable	22	41
Decrease in other assets	--	395
Increase in accounts payable and accrued expenses	8,898	3,068
Increase in deferred rent	46	45
Decrease in deferred revenue	(76)	(76)
Net cash used in operating activities	(62,226)	(49,130)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of equipment	(58)	(2)
Investment in held-to-maturity securities	(6,965)	--
Proceeds from maturity of short-term securities	14,400	11,000
Net cash provided by investing activities		

	7,377	10,998
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from the exercise of warrants	--	2,143
Proceeds from sale of common stock, net	104,453	88,562
Net cash provided by financing activities	104,453	90,705
NET INCREASE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	49,604	52,573
CASH, CASH EQUIVALENTS AND RESTRICTED CASH AT BEGINNING OF PERIOD	57,305	25,614
CASH, CASH EQUIVALENTS AND RESTRICTED CASH AT END OF PERIOD	\$106,909	\$78,187
Reconciliation to amounts on consolidated balance sheets:		
Cash and cash equivalents	\$105,672	\$77,602
Restricted Cash	1,237	585
Total cash, cash equivalents and restricted cash	\$106,909	\$78,187
NONCASH TRANSACTIONS		
Accrued financing cost	\$--	\$234
Reclassification of deferred financing costs to additional paid-in capital	\$--	\$(3)

The accompanying notes are an integral part of the condensed consolidated financial statements.

TG Therapeutics, Inc.
Notes to Condensed Consolidated Financial Statements (unaudited)

Unless the context requires otherwise, references in this report to “TG,” the “Company,” “we,” “us” and “our” refer to TG Therapeutics, Inc. and our subsidiaries.

NOTE 1 – ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Description of Business

We are a biopharmaceutical company focused on the acquisition, development and commercialization of novel treatments for B-cell malignancies and autoimmune diseases. Currently, we are developing two therapies targeting hematologic malignancies. TG-1101 (ublrituximab) is a novel, glycoengineered monoclonal antibody that targets a unique epitope on the CD20 antigen found on mature B-lymphocytes. We are also developing TGR-1202 (umbralisib), an orally available PI3K delta inhibitor. The delta isoform of PI3K is strongly expressed in cells of hematopoietic origin and is believed to be important in the proliferation and survival of B-lymphocytes. Both TG-1101 and TGR-1202, or the combination of which is referred to as "U2," are in Phase 3 clinical development for patients with hematologic malignancies, with TG-1101 also in Phase 3 clinical development for Multiple Sclerosis. Additionally, we have recently brought our anti-PD-L1 monoclonal antibody into Phase 1 development and aim to bring additional pipeline assets into the clinic in the future.

We also actively evaluate complementary products, technologies and companies for in-licensing, partnership, acquisition and/or investment opportunities. To date, we have not received approval for the sale of any of our drug candidates in any market and, therefore, have not generated any product sales from our drug candidates.

The accompanying unaudited condensed consolidated financial statements were prepared in accordance with U.S. generally accepted accounting principles, or GAAP, for interim financial information and with the instructions to Quarterly Report on Form 10-Q and Article 10 of Regulation S-X of the Exchange Act. Accordingly, they may not include all of the information and footnotes required by GAAP for complete financial statements. All adjustments that are, in the opinion of management, of a normal recurring nature and are necessary for a fair presentation of the condensed consolidated financial statements have been included. Nevertheless, these condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements contained in our Annual Report on Form 10-K for the year ended December 31, 2017. The accompanying condensed consolidated December 31, 2017 balance sheet has been derived from these statements. The results of operations for the six months ended June 30, 2018 are not necessarily indicative of the results that may be expected for the entire fiscal year or any other interim period.

Certain reclassifications have been made to the prior period unaudited condensed consolidated financial statements to conform to the current period presentation, including:

Presentation of restricted cash on the condensed consolidated statements of cash flows for the six months ended June 30, 2017, as a result of the adoption of Accounting Standards Update No. 2016-18 in the first quarter of 2018.

Liquidity and Capital Resources

We have incurred operating losses since our inception and expect to continue to incur operating losses for the foreseeable future and, may never become profitable. As of June 30, 2018, we have an accumulated deficit of approximately \$440.5 million.

Our major sources of cash have been proceeds from the private placement and public offering of equity securities. We have not yet commercialized any of our drug candidates and cannot be sure if we will ever be able to do so. Even if we commercialize one or more of our drug candidates, we may not become profitable. Our ability to achieve profitability depends on many factors, including our ability to obtain regulatory approval for our drug candidates; successfully completing any post-approval regulatory obligations; and successfully commercializing our drug candidates alone or in partnership. We may continue to incur substantial operating losses even if we begin to generate revenues from our drug candidates.

As of June 30, 2018, we had approximately \$126.3 million in cash, cash equivalents, investment securities, and interest receivable. The Company believes its cash, cash equivalents, investment securities, and interest receivable on hand as of June 30, 2018 combined with the proceeds raised subsequent to the quarter end will be sufficient to fund the Company's planned operations into the fourth quarter of 2019. The actual amount of cash that we will need to operate is subject to many factors, including, but not limited to, the timing, design and conduct of clinical trials for our drug candidates. We are dependent upon significant future financing to provide the cash necessary to execute our current strategic plan, including the commercialization of any of our drug candidates (see Note 5 for further details).

Our common stock is listed on the Nasdaq Capital Market and trades under the symbol "TGTX."

Recently Issued Accounting Standards

In July 2018, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2018-11, "Leases - Targeted Improvements" ("ASU 2018-11") as an update to ASU 2016-02, Leases ("ASU 2016-02" or "Topic 842") issued on February 25, 2016. ASU 2016-02 is effective for public business entities for fiscal years beginning January 1, 2019. ASU 2016-02 required companies to adopt the new leases standard at the beginning of the earliest period presented in the financial statements, which is January 1, 2017, using a modified retrospective transition method where lessees must recognize lease assets and liabilities for all leases even though those leases may have expired before the effective date of January 1, 2017. Lessees must also provide the new and enhanced disclosures for each period presented, including the comparative periods.

ASU 2018-11 provides an entity with an additional (and optional) transition method to adopt the new leases standard. Under this new transition method, an entity initially applies the new leases standard at the adoption date and recognizes a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. Consequently, an entity's reporting for the comparative periods presented in the financial statements in which it adopts the new leases standard will continue to be in accordance with current GAAP (Topic 840, Leases). An entity that elects this additional (and optional) transition method must provide the required Topic 840 disclosures for all periods that continue to be in accordance with Topic 840. The amendments do not change the existing disclosure requirements in Topic 840. An entity shall apply the effects of modification using one of the following two methods:

Retrospectively to each prior reporting period presented in the financial statements with the cumulative effect of initially applying ASU 2018-11 recognized at the beginning of the earliest comparative period presented. Under this transition method, the application date shall be the later of the beginning of the earliest period presented in the financial statements and the commencement date of the lease.

Retrospectively at the beginning of the period of adoption through a cumulative-effect adjustment. Under this transition method, the application date shall be the beginning of the reporting period in which the entity first applies ASU 2018-11.

ASU 2018-11 is effective for public business entities for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years, with earlier adoption permitted. We are currently evaluating the impact the adoption of ASU 2018-11 will have on our consolidated financial statements.

In June 2018, the FASB issued ASU No. 2018-07, "Improvements to Nonemployee Share-Based Payment Accounting" ("ASU 2018-07"). ASU 2018-07 expands the scope of FASB Topic 718, Compensation – Stock Compensation ("Topic 718") to include share-based payment transactions for acquiring goods and services from nonemployees. An entity should only remeasure equity-classified awards for which a measurement date has not been established through a cumulative-effect adjustment to retained earnings as of the beginning of the fiscal year of adoption. Upon transition, the entity is required to measure these nonemployee awards at fair value as of the adoption date. The entity must not remeasure assets that are completed. Disclosures required at transition include the nature of and reason for the change in accounting principle and, if applicable, quantitative information about the cumulative effect of the change on retained earnings or other components of equity.

ASU 2018-07 is effective for public business entities for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. Early adoption is permitted, but no earlier than an entity's adoption date of Topic 606. We are currently evaluating the impact the adoption of ASU 2018-07 will have on our consolidated financial statements.

In May 2017, the FASB issued ASU No. 2017-09, “Scope of Modification Accounting” (“ASU 2017-09”). ASU 2017-09 provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting. An entity should account for the effects of a modification unless all the following are met:

The fair value (or calculated value or intrinsic value, if such an alternative measurement method is used) of the modified award is the same as the fair value (or calculated value or intrinsic value, if such an alternative measurement method is used) of the original award immediately before the original award is modified. If the modification does not affect any of the inputs to the valuation technique that the entity uses to value the award, the entity is not required to estimate the value immediately before and after the modification.

The vesting conditions of the modified award are the same as the vesting conditions of the original award immediately before the original award is modified.

The classification of the modified award as an equity instrument or a liability instrument is the same as the classification of the original award immediately before the original award is modified.

ASU 2017-09 is effective for annual and interim periods beginning on or after December 15, 2017. Early adoption is permitted for public business entities for reporting periods for which financial statements have not yet been issued, and all other entities for reporting periods for which financial statements have not yet been made available for issuance. The amendments should be applied prospectively to an award modified on or after the adoption date. The Company adopted ASU 2017-09 on January 1, 2018. The adoption of ASU 2017-09 did not have a material effect on our consolidated financial statements as of June 30, 2018.

In January 2017, the FASB issued ASU No. 2017-01, “FASB Clarifies the Definition of a Business” (“ASU 2017-01”). ASU 2017-01 clarifies the definition of a business in ASC 805. The amendments in ASU 2017-01 are intended to make application of the guidance more consistent and cost-efficient. The amendments in ASU 2017-01:

Provide a screen to determine when a set of assets and activities is not a business. The screen requires that when substantially all of the fair value of the gross assets acquired (or disposed of) is concentrated in a single identifiable asset or a group of similar identifiable assets, the set is not a business. This screen reduces the number of transactions that need to be further evaluated.

Provide that if the screen is not met, (1) to be considered a business, a set must include, at a minimum, an input and a substantive process that together significantly contribute to the ability to create output and (2) remove the evaluation of whether a market participant could replace missing elements. The amendments provide a framework to assist entities in evaluating whether both an input and a substantive process are present. The framework includes two sets of criteria to consider that depend on whether a set has outputs. Although outputs are not required for a set to be a business, outputs generally are a key element of a business; therefore, the Board has developed more stringent criteria for sets without outputs.

Narrow the definition of the term output so that the term is consistent with how outputs are described in Topic 606.

ASU 2017-01 is effective for annual and interim periods beginning after December 15, 2017, with early adoption permitted for transactions that occurred before the issuance date or effective date of the standard if the transactions were not reported in financial statements that have been issued or made available for issuance. The Company adopted ASU 2017-01 on January 1, 2018. The adoption of ASU 2017-01 did not have a material effect on our consolidated financial statements as of June 30, 2018.

In November 2016, the FASB issued ASU No. 2016-18, “Statement of Cash Flows – Restricted Cash” (“ASU 2016-18”). ASU 2016-18 requires that a statement of cash flows explain the change during the period for the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. ASU 2016-18 does not provide a definition of restricted cash or restricted cash equivalents, and does not change the balance sheet presentation for such items. The Company adopted ASU 2016-18 on January 1, 2018. The adoption of ASU 2016-18 did not have a material effect on our consolidated financial statements as of June 30, 2018.

In May 2014, the FASB issued ASU No. 2014-09, “Revenue from Contracts with Customers” (Topic 606) (“ASU 2014-09” or “ASC 606”), which supersedes all existing revenue recognition requirements, including most industry-specific guidance. ASU 2014-09 provides a single set of criteria for revenue recognition among all industries. The new standard requires a company to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that the Company expects to receive for those goods or services.

ASU 2014-09 includes guidance for determining whether a license transfers to a customer at a point in time or over time based on the nature of the entity’s promise to the customer. To determine whether the entity’s promise is to provide a right to access its intellectual property or a right to use its intellectual property, the entity should consider the nature of the intellectual property to which the customer will have rights.

ASU 2014-09 is effective for interim and annual periods beginning after December 15, 2017. The standard allows for two transition methods - full retrospective, in which the standard is applied to each prior reporting period presented, or modified retrospective, in which the cumulative effect of initially applying the standard is recognized at the date of initial adoption. The Company adopted ASU 2014-09 on January 1, 2018, using the modified retrospective approach. The adoption of ASU 2014-09 did not have a material effect on our condensed consolidated financial statements as of June 30, 2018.

Other pronouncements issued by the FASB or other authoritative accounting standards with future effective dates are either not applicable or not significant to our consolidated financial statements.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and judgments that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the applicable reporting period. Actual results could differ from those estimates. Such differences could be material to the consolidated financial statements.

Cash and Cash Equivalents

We treat liquid investments with original maturities of three months or less when purchased as cash and cash equivalents.

Restricted Cash

We record cash pledged or held in trust as restricted cash. As of June 30, 2018 and December 31, 2017, we have approximately \$1.2 million and \$0.6 million, respectively, of restricted cash pledged to secure a line of credit as a security deposit for an Office Agreement (see Note 8).

Investment Securities

Investment securities at June 30, 2018 and December 31, 2017 consist of short-term government securities. We classify these securities as held-to-maturity. Held-to-maturity securities are those securities in which we have the ability and intent to hold the security until maturity. Held-to-maturity securities are recorded at amortized cost, adjusted for the amortization or accretion of premiums or discounts. Premiums and discounts are amortized or accreted over the life of the related held-to-maturity security as an adjustment to yield using the effective interest method.

A decline in the market value of any investment security below cost, that is deemed to be other than temporary, results in a reduction in the carrying amount to fair value. The impairment is charged to operations and a new cost basis for the security is established. Other-than-temporary impairment charges would be included in interest and other (income) expense, net. Dividend and interest income are recognized when earned.

Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents and short-term investments. The Company maintains its cash and cash equivalents and short-term investments with high-credit quality financial institutions. At times, such amounts may exceed federally-insured limits.

Revenue Recognition

We recognize license revenue in accordance with the revenue recognition guidance of ASC 606. We analyze each element of our licensing agreement to determine the appropriate revenue recognition. The terms of the license agreement may include payments to us of non-refundable up-front license fees, milestone payments if specified objectives are achieved, and/or royalties on product sales. We recognize revenue from upfront payments over the period of significant involvement under the related agreements unless the fee is in exchange for a promise to transfer more than one good or service to the customer, in which case the Company would account for each promised good or service as a performance obligation only if it is (1) distinct or (2) a series of distinct goods or services that are substantially the same and have the same pattern of transfer. For each performance obligation, the Company would determine whether we satisfy the performance obligation over time by transferring control of a good or service over time. To determine whether the Company's promise is to provide a right to access its intellectual property or a right to use its intellectual property, the Company would consider the nature of the intellectual property to which the customer will have rights. The Company has symbolic intellectual property, derived from its association with the Company's ongoing activities, including its ordinary business activities. We recognize milestone payments as revenue upon the achievement of specified milestones only if (1) the milestone payment is non-refundable, (2) substantive effort is involved in achieving the milestone, (3) the amount of the milestone is reasonable in relation to the effort expended or the risk associated with achievement of the milestone, and (4) the milestone is at risk for both parties. If any of these conditions are not met, we defer the milestone payment and recognize it as revenue over the estimated period of performance under the contract.

Research and Development Costs

Generally, research and development costs are expensed as incurred. Non-refundable advance payments for goods or services that will be used or rendered for future research and development activities are deferred and amortized over the period that the goods are delivered or the related services are performed, subject to an assessment of recoverability. We make estimates of costs incurred in relation to external clinical research organizations, or CROs, and clinical site costs. We analyze the progress of clinical trials, including levels of patient enrollment, invoices

received and contracted costs when evaluating the adequacy of the amount expensed and the related prepaid asset and accrued liability. Significant judgments and estimates must be made and used in determining the accrued liability balance and expense in any accounting period. We review and accrue CRO expenses and clinical trial study expenses based on work performed and rely upon estimates of those costs applicable to the stage of completion of a study. Accrued CRO costs are subject to revisions as such trials progress to completion. Revisions are charged to expense in the period in which the facts that give rise to the revision become known. With respect to clinical site costs, the financial terms of these agreements are subject to negotiation and vary from contract to contract. Payments under these contracts may be uneven, and depend on factors such as the achievement of certain events, the successful recruitment of patients, the completion of portions of the clinical trial or similar conditions. The objective of our policy is to match the recording of expenses in our financial statements to the actual services received and efforts expended. As such, expense accruals related to clinical site costs are recognized based on our estimate of the degree of completion of the event or events specified in the specific clinical study or trial contract.

Prepaid research and development in our consolidated balance sheets includes, among other things, costs related to agreements with CRO's, certain costs to third party service providers related to development and manufacturing services as well as clinical development. These agreements often require payments in advance of services performed or goods received. Accordingly, as of June 30, 2018 and December 31, 2017, we recorded approximately \$8.9 million and \$8.1 million, respectively, in prepaid research and development related to such advance agreements.

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, operating losses and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period that includes the enactment date. If the likelihood of realizing the deferred tax assets or liability is less than “more likely than not,” a valuation allowance is then created.

Stock-Based Compensation

We recognize all share-based payments to employees and non-employee directors (as compensation for service) as noncash compensation expense in the condensed consolidated financial statements based on the fair values of such payments. Stock-based compensation expense recognized each period is based on the value of the portion of share-based payment awards that is ultimately expected to vest during the period. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

For share-based payments to consultants and other third-parties (including related parties), noncash compensation expense is determined at the “measurement date.” The expense is recognized over the vesting period of the award. Until the measurement date is reached, the total amount of compensation expense remains uncertain. We record compensation expense based on the fair value of the award at the reporting date. The awards to consultants and other third-parties (including related parties) are then revalued, or the total compensation is recalculated based on the then current fair value, at each subsequent reporting date.

In addition, because some of the restricted stock issued to employees, consultants and other third-parties vest upon achievement of certain milestones, the total expense is uncertain. Compensation expense for such awards that vest upon the achievement of milestones is recognized when the achievement of such milestones becomes probable.

Basic and Diluted Net Loss Per Common Share

Basic net loss per share of our common stock is calculated by dividing net loss applicable to the common stock by the weighted-average number of our common stock outstanding for the period. Diluted net loss per share of common stock is the same as basic net loss per share of common stock since potentially dilutive securities from stock options, stock warrants and convertible preferred stock would have an antidilutive effect either because we incurred a net loss during the period presented or because such potentially dilutive securities were out of the money and the Company realized net income during the period presented. The following outstanding shares of common stock equivalents were excluded from the computation of net loss per share attributable to common stockholders for the periods presented because including them would have been antidilutive:

	Three and Six Months Ended June 30,	
	2018	2017
Unvested restricted shares	4,589,940	4,275,762

Stock options	560,000	--
Shares issuable upon note conversion	15,950	15,181
Total	5,165,890	4,290,943

Long-Lived Assets and Goodwill

Long-lived assets are reviewed for potential impairment when circumstances indicate that the carrying value of long-lived tangible and intangible assets with finite lives may not be recoverable. Management's policy in determining whether an impairment indicator exists, a triggering event, comprises measurable operating performance criteria as well as qualitative measures. If an analysis is necessitated by the occurrence of a triggering event, we make certain assumptions in determining the impairment amount. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized.

Goodwill is reviewed for impairment annually, or earlier when events arise that could indicate that an impairment exists. We test for goodwill impairment using a two-step process. The first step compares the fair value of the reporting unit with the unit's carrying value, including goodwill. When the carrying value of the reporting unit is greater than fair value, the unit's goodwill may be impaired, and the second step must be completed to measure the amount of the goodwill impairment charge, if any. In the second step, the implied fair value of the reporting unit's goodwill is compared with the carrying amount of the unit's goodwill. If the carrying amount is greater than the implied fair value, the carrying value of the goodwill must be written down to its implied fair value. We will continue to perform impairment tests annually, at December 31, and whenever events or changes in circumstances suggest that the carrying value of an asset may not be recoverable.

Rent Expense and Deferred Rent

Rent expense and lease incentives, including landlord construction allowances, are recognized on a straight-line basis over the lease term, commencing generally on the date the Company takes possession of the leased property. The Company records lease incentives as deferred rent and recognizes the lease incentives as reductions of rental expense. The unamortized portion of deferred rent is included in deferred rent in the condensed consolidated balance sheets.

Obligations of domestic governmental agencies (maturing between January 2018 and November 2018) (held-to-maturity)	\$27,999	--	\$35	\$27,964
Total short-term investment securities	\$27,999	--	\$35	\$27,964

NOTE 4 – FAIR VALUE MEASUREMENTS

We measure certain financial assets and liabilities at fair value on a recurring basis in the condensed consolidated financial statements. The fair value hierarchy ranks the quality and reliability of inputs, or assumptions, used in the determination of fair value and requires financial assets and liabilities carried at fair value to be classified and disclosed in one of the following three categories:

Level 1 – quoted prices in active markets for identical assets and liabilities;

Level 2 – inputs other than Level 1 quoted prices that are directly or indirectly observable; and

Level 3 – unobservable inputs that are not corroborated by market data.

As of June 30, 2018 and December 31, 2017, the fair values of cash and cash equivalents, restricted cash, accounts payable, and notes and interest payable, approximate their carrying value.

At the time of our merger (we were then known as Manhattan Pharmaceuticals, Inc. (“Manhattan”)) with Ariston Pharmaceuticals, Inc. (“Ariston”) in March 2010, Ariston issued \$15.5 million of five-year 5% notes payable (the “5% Notes”) in satisfaction of several note payable issuances. The 5% Notes and accrued and unpaid interest thereon are convertible at the option of the holder into common stock at the conversion price of \$1,125 per share. Ariston agreed to make quarterly payments on the 5% Notes equal to 50% of the net product cash flow received from the exploitation or commercialization of Ariston’s product candidates, AST-726 and AST-915. We have no obligations under the 5% Notes aside from (a) 50% of the net product cash flows from Ariston’s product candidates, if any, payable to noteholders; and (b) the conversion feature, discussed above.

The cumulative liability including accrued and unpaid interest of the 5% Notes was approximately \$17.9 million at June 30, 2018 and \$17.5 million at December 31, 2017. No payments have been made on the 5% Notes as of June 30, 2018.

In December 2011, we elected the fair value option for valuing the 5% Notes. The fair value option was elected in order to reflect in our financial statements the assumptions that market participants use in evaluating these financial instruments.

As of December 31, 2013, as a result of expiring intellectual property rights and other factors, it was determined that net product cash flows from AST-726 were unlikely. As we have no other obligations under the 5% Notes aside from the net product cash flows and the conversion feature, the conversion feature was used to estimate the 5% Notes’ fair value as of June 30, 2018 and December 31, 2017. The assumptions, assessments and projections of future revenues are subject to uncertainties, difficult to predict, and require significant judgment. The use of different assumptions, applying different judgment to inherently subjective matters and changes in future market conditions could result in significantly different estimates of fair value and the differences could be material to our condensed consolidated financial statements.

The following tables provide the fair value measurements of applicable financial liabilities as of June 30, 2018 and December 31, 2017:

(in thousands) Financial liabilities at fair value as of June 30, 2018

	Level 1	Level 2	Level 3	Total
5% Notes	\$--	\$--	\$210	\$210
Total	\$--	\$--	\$210	\$210

Financial liabilities at fair value as of December 31, 2017

Level 1 Level 2 Level 3 Total

5% Notes	\$--	\$--	\$128	\$128
Total	\$--	\$--	\$128	\$128

The Level 3 amounts above represent the fair value of the 5% Notes and related accrued interest.

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The following table summarizes the changes in Level 3 instruments during the six months ended June 30, 2018:

(in thousands)

Fair value at December 31, 2017	\$128
Interest accrued on face value of 5% Notes	436
Change in fair value of Level 3 liabilities	(354)
Fair value at June 30, 2018	\$210

The change in the fair value of the Level 3 liabilities is reported in other (income) expense in the accompanying condensed consolidated statements of operations.

NOTE 5 - STOCKHOLDERS' EQUITY

Preferred Stock

Our amended and restated certificate of incorporation authorizes the issuance of up to 10,000,000 shares of preferred stock, \$0.001 par value, with rights senior to those of our common stock, issuable in one or more series. Upon issuance, we can determine the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting any series or the designation of such series, any or all of which may be greater than the rights of common stock.

Common Stock

Our amended and restated certificate of incorporation authorizes the issuance of up to 150,000,000 shares of \$0.001 par value common stock.

In May 2017, we filed a shelf registration statement on Form S-3 (the "2017 S-3"), which was declared effective in June 2017, replacing the 2015 S-3. Under the 2017 S-3, the Company may sell up to a total of \$300 million of its securities. In connection with the 2017 S-3, we entered into an At-the-Market Issuance Sales Agreement (the "2017 ATM") with Jefferies LLC, Cantor Fitzgerald & Co., FBR Capital Markets & Co., SunTrust Robinson Humphrey, Inc., Raymond James & Associates, Inc., Ladenburg Thalmann & Co. Inc. and H.C. Wainwright & Co., LLC (each a "2017 Agent" and collectively, the "2017 Agents"), relating to the sale of shares of our common stock. Under the 2017 ATM we pay the 2017 Agents a commission rate of up to 3.0% of the gross proceeds from the sale of any shares of common stock.

In July 2018, we filed a shelf registration statement on Form S-3 (the "2018 S-3") pursuant to the Joint Venture and License Option Agreement, dated June 18, 2018, by and between TG Therapeutics, Inc. and Novimmune S.A. ("Novimmune"), pursuant to which we issued 216,294 common shares to Novimmune. The 2018 S-3 was declared effective in July 2018.

During the six months ended June 30, 2018, we sold a total of 7,733,949 shares of common stock under the 2017 ATM for aggregate total gross proceeds of approximately \$106.3 million at an average selling price of \$13.75 per share, resulting in net proceeds of approximately \$104.5 million after deducting commissions and other transactions costs.

Subsequent to the second quarter, from July 1, 2018 through August 7, 2018, we sold an aggregate of 358,000 shares of common stock pursuant to the 2017 ATM for total gross proceeds of approximately \$4.7 million at an average

selling price of \$13.00 per share, resulting in net proceeds of approximately \$4.6 million after deducting commissions and other transactions costs.

The 2017 S-3 is currently our only active shelf registration statement, pursuant to which we can issue shares in an offering. After deducting shares already sold there is approximately \$145.9 million of common stock that remains available for sale under the 2017 S-3. We may offer the securities under the 2017 S-3 from time to time in response to market conditions or other circumstances if we believe such a plan of financing is in the best interests of our stockholders. We believe that the 2017 S-3 provides us with the flexibility to raise additional capital to finance our operations as needed.

Equity Incentive Plans

The TG Therapeutics, Inc. Amended and Restated 2012 Incentive Plan (“2012 Incentive Plan”) was approved by stockholders in June 2018. Pursuant to this amendment, 6,000,000 shares were added to the 2012 Incentive Plan. As of June 30, 2018, 560,000 options were outstanding and up to an additional 4,654,278 shares may be issued under the 2012 Incentive Plan.

Effective as of January 1, 2017, we entered into an amendment (the “Amendment”) to the employment agreement entered as of December 15, 2011 (together with the Amendment, the “Employment Agreement”) with Michael S. Weiss, our Executive Chairman and Chief Executive Officer and President of the Company. Under the Amendment, Mr. Weiss will remain as Chief Executive Officer and President, removing the interim status. Simultaneously, we entered into a Strategic Advisory Agreement (the “Advisory Agreement”) with Caribe BioAdvisors, LLC (the “Advisor”) owned by Mr. Weiss to provide the services of Mr. Weiss as Chairman of the Board and as Executive Chairman. As part of the Amendment, Mr. Weiss also agreed to forfeit 3,381,866 restricted shares previously granted under the Employment Agreement that were predominantly subject to time-based vesting over the next three years. Simultaneously, (i) Mr. Weiss was issued 418,371 restricted shares under the Employment Agreement that vest in 2018 and 2019 and (ii) the Advisor was issued 2,960,000 restricted shares under the Advisory Agreement that vested on market capitalization thresholds ranging from \$375 million to \$750 million. In accordance with GAAP, there was no incremental stock compensation expense recognition as a result of the modification.

Stock Options

The fair value of stock options granted is estimated at the date of grant using the Black-Scholes pricing model. The expected term of options granted is derived from historical data and the expected vesting period. Expected volatility is based on the historical volatility of our common stock. The risk-free interest rate is based on the U.S. Treasury yield for a period consistent with the expected term of the option in effect at the time of the grant. We have assumed no expected dividend yield, as dividends have never been paid to stock or option holders and will not be paid for the foreseeable future. We granted 560,000 and zero stock options during the six months ended June 30, 2018 and 2017, respectively.

The following table summarizes stock option activity for the three months ended June 30, 2018:

	Number of shares	Weighted- average exercise price	Weighted- average Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2017	--	\$--	--	\$--
Granted	560,000	11.56		
Exercised	--	--		
Forfeited	--	--		
Expired	--	--		
Outstanding at June 30, 2018	560,000	\$11.56	9.65	\$897,250
Exercisable at June 30, 2018	--	\$11.56	--	\$--

As of June 30, 2018, the stock options outstanding include options granted to both employees and non-employees which are milestone-based and vest upon certain corporate milestones. Stock-based compensation will be recorded if and when a milestone occurs.

Restricted Stock

Certain employees, directors and consultants have been awarded restricted stock. The restricted stock vesting consists of milestone and time-based vesting. The following table summarizes restricted share activity for the six months ended June 30, 2018:

	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2017	6,321,643	\$7.17
Granted	1,420,511	13.32
Vested	(1,521,550)	9.46
Forfeited	(130,661)	8.30
Outstanding at June 30, 2018	6,089,943	\$8.01

Total expense associated with restricted stock grants was approximately \$4.3 million and \$1.5 million during the three months ended June 30, 2018 and 2017, respectively, and \$11.6 million, and \$7.5 million during the six months ended June 30, 2018 and 2017, respectively. As of June 30, 2018, there was approximately \$11.0 million of total unrecognized compensation cost related to unvested time-based restricted stock, which is expected to be recognized over a weighted-average period of 1.2 years. The unrecognized compensation amount does not include, as of June 30, 2018, 1,128,011 shares of restricted stock outstanding which are milestone-based and vest upon certain corporate milestones; and 2,224,167 shares of restricted stock outstanding issued to non-employees, the expense for which is determined each reporting period at the measurement date. The expense for non-employee awards is recognized over the vesting period of the award. Until the measurement date is reached, the total amount of compensation expense remains uncertain. We record compensation expense based on the fair value of the award at the reporting date.

NOTE 6 – NOTES PAYABLE

The following is a summary of notes payable:

(in thousands)	June 30, 2018			December 31, 2017		
	Current portion, net	Non-current portion, net	Total	Current portion, net	Non-current portion, net	Total
Convertible 5% Notes Payable	\$210	\$-	\$210	\$128	\$-	\$128
Total	\$210	\$-	\$210	\$128	\$-	\$128

Convertible 5% Notes Payable

The 5% Notes and accrued and unpaid interest thereon are convertible at the option of the holder into common stock at the conversion price of \$1,125 per share. We have no obligation under the 5% Notes aside from (a) 50% of the net product cash flows from Ariston's product candidates, if any, payable to noteholders; and (b) the conversion feature, discussed above. Interest accrues monthly, is added to principal on an annual basis, every March 8, and is payable at maturity, which was March 8, 2015 (see Note 4 for further details).

The cumulative liability including accrued and unpaid interest of these notes was approximately \$17.9 million at June 30, 2018 and \$17.5 million at December 31, 2017. No payments have been made on the 5% Notes as of June 30, 2018.

In December 2011, we elected the fair value option for valuing the 5% Notes. The fair value option was elected in order to reflect in our financial statements the assumptions that market participants use in evaluating these financial instruments (see Note 4 for further details).

NOTE 7 – LICENSE AGREEMENTS

TG-1101

In November 2012, we entered into an exclusive (within the territory) sublicense agreement with Ildong relating to the development and commercialization of TG-1101 in South Korea and Southeast Asia. Under the terms of the sublicense agreement, Ildong has been granted a royalty bearing, exclusive right, including the right to grant sublicenses, to develop and commercialize TG-1101 in South Korea, Taiwan, Singapore, Indonesia, Malaysia, Thailand, Philippines, Vietnam, and Myanmar.

An upfront payment of \$2.0 million, which was received in December 2012, net of \$0.3 million of income tax withholdings, is being recognized as license revenue on a straight-line basis over the life of the agreement, which is through the expiration of the last licensed patent right or 15 years after the first commercial sale of a product in such country, unless the agreement is earlier terminated, and represents the estimated period over which we will have certain ongoing responsibilities under the sublicense agreement. We recorded license revenue of approximately \$38,000 for each of the three months ended June 30, 2018 and 2017, and \$76,000 for each of the six months ended June 30, 2018 and 2017 and, at June 30, 2018 and December 31, 2017, have deferred revenue of approximately \$1.1 million and \$1.2 million, respectively, associated with this \$2.0 million payment (approximately \$152,000 of which has been classified in current liabilities at June 30, 2018 and December 31, 2017).

We may receive up to an additional \$5.0 million in payments upon the achievement of pre-specified milestones. In addition, upon commercialization, Ildong will make royalty payments to us on net sales of TG-1101 in the sublicense territory.

TG-1701: BTK

In January 2018, we entered into a global exclusive license agreement with Jiangsu Hengrui Medicine Co. ("Jiangsu"), to acquire worldwide intellectual property rights, excluding Asia but including Japan, and for the research, development, manufacturing, and commercialization of products containing or comprising of any of Jiangsu's Bruton's Tyrosine Kinase inhibitors containing the compounds of either TG1701 (SHR1459 or EBI1459) or TG1702 (SHR1266 or EBI1266). Pursuant to the agreement, in April 2018, we paid Jiangsu an upfront fee of \$1.0 million in our common stock. Jiangsu is eligible to receive milestone payments totaling approximately \$350 million upon and subject to the achievement of certain milestones. Various provisions allow for payments in conjunction with the

agreement to be made in cash or our common stock, while others limit the form of payment. Royalty payments in the low double digits are due on net sales of licensed products and revenue from sublicenses.

TG-1801: anti-CD47/anti-CD19

In June 2018, we entered into a Joint Venture and License Option Agreement with Novimmune SA (“Novimmune”) to collaborate on the development and commercialization of Novimmune’s novel first-in-class anti-CD47/anti-CD19 bispecific antibody known as TG-1801 (previously NI-1701). The companies will jointly develop the product on a worldwide basis, focusing on indications in the area of hematologic B-cell malignancies. We serve as the primary responsible party for the development, manufacturing and commercialization of the product. Pursuant to the agreement, in June 2018 we paid Novimmune an upfront payment of \$3.0 million in our common stock. Further milestone payments will be paid based on early clinical development, and the Company will be responsible for the costs of clinical development of the product through the end of the Phase 2 clinical trials, after which the Company and Novimmune will be jointly responsible for all development and commercialization costs. The Company and Novimmune will each maintain an exclusive option, exercisable at specific times during development, for the Company to license the rights to TG-1801, in which case Novimmune is eligible to receive additional milestone payments totaling approximately \$185 million as well as tiered royalties on net sales in the high single to low double digits upon and subject to the achievement of certain milestones.

NOTE 8 – RELATED PARTY TRANSACTIONS

LFB Biotechnologies

On January 30, 2012, we entered into an exclusive license agreement with LFB Biotechnologies, GTC Biotherapeutics and LFB/GTC LLC, all wholly-owned subsidiaries of LFB Group, relating to the development of ublituximab (the “LFB License Agreement”). In connection with the LFB License Agreement, LFB Group was issued 5,000,000 shares of common stock, and a warrant to purchase 2,500,000 shares of common stock at a purchase price of \$0.001 per share.

Under the terms of the LFB License Agreement, we utilize LFB Group for certain development and manufacturing services. We incurred expenses of approximately \$38,000 and \$400,000 during the three months ended June 30, 2018 and 2017, respectively, and \$0.2 million and \$0.5 million during the six months ended June 30, 2018 and 2017, respectively, which have been included in other research and development expenses in the accompanying condensed consolidated statements of operations. As of June 30, 2018 and December 31, 2017, we had approximately \$37,000 and zero, respectively, recorded in accounts payable related to the LFB License Agreement.

Other Parties

In October 2014, we entered into an agreement (the “Office Agreement”) with Fortress Biotech, Inc. (“FBIO”), to occupy approximately 45% of the 24,000 square feet of New York City office space leased by FBIO, which is now our corporate headquarters. The Office Agreement requires us to pay our respective share of the average annual rent and other costs of the 15-year lease. We approximate an average annual rental obligation of \$1.1 million under the Office Agreement. We began to occupy this new space in April 2016, with rental payments beginning in the third quarter of 2016. During the three and six months ended June 30, 2018, we recorded rent expense of approximately \$0.3 million and \$0.7 million, respectively, and at June 30, 2018, have deferred rent of approximately \$1.4 million. As of June 30, 2018 and December 31, 2017, we have approximately \$1.2 million and \$0.6 million, respectively, of restricted cash pledged to secure a line of credit as a security deposit related to the Office Agreement. Mr. Weiss, our Executive Chairman and CEO, is also Executive Vice Chairman of FBIO.

Under the Office Agreement, we agreed to pay FBIO our portion of the build out costs, which have been allocated to us at the 45% rate mentioned above. The allocated buildout costs have been recorded in Leasehold Interest and will be amortized over the 15 year term of the Office Agreement. After an initial commitment of the 45% rate for a period of three (3) years, we and FBIO will determine actual office space utilization annually and if our utilization differs from the amount we have been billed, we will either receive credits or be assessed incremental utilization charges. As of June 30, 2018, we had approximately \$0.4 million recorded in accounts payable related to FBIO, none of which related to rent and build-out costs.

In July 2015, we entered into a Shared Services Agreement (the “Shared Services Agreement”) with FBIO to share the cost of certain services such as facilities use, personnel costs and other overhead and administrative costs. This Shared Services Agreement requires us to pay our respective share of services utilized. In connection with the Shared Services Agreement, we incurred expenses of approximately \$1.1 million and \$0.7 million for shared services for the six months ended June 30, 2018 and 2017, respectively, and expenses of approximately \$0.7 million and \$0.4 million for the three months ended June 30, 2018 and 2017, primarily related to shared personnel.

In May 2016, as part of a broader agreement with Jubilant Biosys (“Jubilant”), an India-based biotechnology company, we entered into a sublicense agreement (“JBET Agreement”) with Checkpoint Therapeutics, Inc. (“Checkpoint”), a subsidiary of FBIO, for the development and commercialization of Jubilant’s novel BET inhibitor program in the field of hematological malignancies. We paid Checkpoint an up-front licensing fee of \$1.0 million in

July 2016 and incurred expenses of \$0.2 million in March 2017 for the first milestone achievement as part of the JBET Agreement which is recorded in other research and development in the accompanying consolidated statement of operations. As of June 30, 2018 and 2017, we had approximately \$0.1 million and \$0.8 million, respectively, recorded in accounts payable, related mostly to the JBET Agreement. Mr. Weiss is also the Executive Chairman of Checkpoint.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis contains forward-looking statements about our plans and expectations of what may happen in the future. Forward-looking statements are based on a number of assumptions and estimates that are inherently subject to significant risks and uncertainties, and our results could differ materially from the results anticipated by our forward-looking statements as a result of many known or unknown factors, including, but not limited to, those factors discussed in "Risk Factors." See also the "Special Cautionary Notice Regarding Forward-Looking Statements" set forth at the beginning of this report.

You should read the following discussion and analysis in conjunction with the unaudited condensed consolidated financial statements, and the related footnotes thereto, appearing elsewhere in this report, and in conjunction with management's discussion and analysis and the audited consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2017.

OVERVIEW

We are a biopharmaceutical company focused on the acquisition, development and commercialization of novel treatments for B-cell malignancies and autoimmune diseases. Currently, we are developing two therapies targeting hematologic malignancies. TG-1101 (ublrituximab) is a novel, glycoengineered monoclonal antibody that targets a unique epitope on the CD20 antigen found on mature B-lymphocytes. We are also developing TGR-1202 (umbralisib), an orally available PI3K delta inhibitor. The delta isoform of PI3K is strongly expressed in cells of hematopoietic origin and is believed to be important in the proliferation and survival of B-lymphocytes. Both TG-1101 and TGR-1202, or the combination which is referred to as "U2," are in Phase 3 clinical development for patients with hematologic malignancies, with TG-1101 also in Phase 3 clinical development for patients with multiple sclerosis. Additionally, we have recently brought our anti-PD-L1 monoclonal antibody into Phase 1 development and aim to bring additional pipeline assets into the clinic in the future.

We also actively evaluate complementary products, technologies and companies for in-licensing, partnership, acquisition and/or investment opportunities. To date, we have not received approval for the sale of any of our drug candidates in any market and, therefore, have not generated any product sales from our drug candidates.

TG-1101 (ublrituximab)

Overview

TG-1101 (ublrituximab) is a chimeric, glycoengineered monoclonal antibody that targets a unique epitope on the CD20 antigen found on the surface of B-lymphocytes developed to aid in the depletion of circulating B-cells. We hold exclusive worldwide rights to develop and commercialize TG-1101 for all indications, except for the territories of France and Belgium which have been retained by LFB Biotechnologies, and South Korea and Southeast Asia which were licensed by us to Ildong in November 2012.

Generally, anti-CD20 antibodies are believed to exert their B-cell depleting effects through three primary mechanisms: antibody dependent cell-mediated cytotoxicity ("ADCC"), complement dependent cytotoxicity ("CDC"), and direct or programmed cell death ("DCD" or "PCD"). TG-1101 has been specifically glycoengineered to enhance ADCC activity, which should enhance its ability to deplete B-cells and may improve its anti-cancer effects when compared to Rituxan®, the leading anti-CD20 monoclonal antibody, which had worldwide sales in 2016 of more than \$7 billion.

Clinical Trials Overview and Recent Developments

Two single-agent, dose-escalation, Phase I studies were undertaken with TG-1101 to establish an optimal dose in patients with Non-Hodgkin's Lymphoma ("NHL") and Chronic Lymphocytic Leukemia ("CLL"). A two part first-in-human Phase I clinical trial was first completed in France in which TG-1101 was evaluated in relapsed or refractory CLL. Subsequently, a single-agent Phase I study was undertaken in the US enrolling patients with both NHL and CLL. In both studies, single agent therapy with TG-1101 was deemed well tolerated by treating investigators and displayed promising clinical activity in relapsed and refractory patients.

In oncology settings, anti-CD20 therapy is generally used in combination with other anti-cancer agents where it demonstrates maximum activity as opposed to single agent usage. As a result, subsequent clinical development for TG-1101 has focused on combination therapy. Currently, our priority combination trials for TG-1101 are:

The GENUINE Trial – a randomized controlled Phase 3 trial evaluating TG-1101 in combination with ibrutinib, for previously treated CLL patients with high risk cytogenetics;

The UNITY-CLL Trial – a randomized controlled Phase 3 trial under Special Protocol Assessment ("SPA") evaluating TG-1101 in combination with TGR-1202, the Company's development stage PI3K delta inhibitor, for patients with front line and previously treated CLL;

The UNITY-NHL Trial – registration-directed Phase 2b clinical study evaluating TGR-1202 alone and in combination with TG-1101 with or without bendamustine, in patients with previously treated Non-Hodgkin's Lymphoma ("NHL"); and

TG-1101 + TGR-1202 + Pembrolizumab for patients with CLL.

In non-oncology settings, anti-CD20 therapy has generally been used as monotherapy. In addition to the above oncology studies, TG-1101 is being evaluated in a Phase 2 study for the treatment of Multiple Sclerosis ("MS") and in an investigator initiated Phase 1 study for the treatment of acute neuromyelitis optica ("NMO") relapses, with additional autoimmune related indications planned to be studied. On August 1, 2017, we announced we had reached an agreement with the U.S. Food and Drug Administration ("FDA") regarding an SPA on the design of two global Phase 3 clinical trials for TG-1101, referred to as the ULTIMATE I and ULTIMATE II Phase 3 clinical trials.

Manufacturing of TG-1101 is currently performed by a contract manufacturer based in the US.

Further details on our priority ongoing trials for TG-1101 are as follows:

TG-1101 + Ibrutinib Phase 3 Study Program – The GENUINE Trial

The GENUINE trial is a randomized controlled clinical trial in patients with previously treated CLL with specific high-risk cytogenetic abnormalities, with patients randomized to receive either TG-1101 plus ibrutinib or ibrutinib alone. In October 2016, we announced revisions to the design of the GENUINE study to accelerate its completion. Initially the study was being conducted pursuant to an SPA with the FDA, and was designed to enroll approximately 330 patients, with a two-part analysis of both overall response rate ("ORR") and progression-free survival ("PFS"). The trial was amended in October 2016 to enroll approximately 120 patients, with the PFS analysis component removed. Following the revisions, the sole primary endpoint of the study is ORR, and the SPA is no longer in effect.

In June 2017, the positive results from our Phase 3 GENUINE trial were presented by Dr. Jeff Sharman, Medical Director, Hematology Research, US Oncology in an oral session during the 53rd American Society of Clinical Oncology ("ASCO") Annual Meeting in Chicago, IL.

This presentation included data from the GENUINE Phase 3 trial, a multicenter, randomized trial, which assessed the efficacy and safety of TG-1101 plus ibrutinib versus ibrutinib alone in patients with high risk CLL. For the trial, high-risk was defined as having any one or more of the following centrally confirmed features: 17p deletion, 11q

deletion or p53 mutation. The GENUINE study was designed to demonstrate the value of adding TG-1101 to ibrutinib monotherapy in high-risk CLL, and was powered to show a statistically significant improvement in ORR of 30%, with a minimal absolute detectable difference between the two arms of approximately 20%.

We continue to follow patients in the GENUINE study for safety and efficacy including Overall Response, MRD and Progression Free Survival ("PFS"). We are currently working on preparing a Biologics License Application for a potential accelerated approval filing for TG-1101 in combination with ibrutinib in previously treated CLL patients with high-risk cytogenetics, which filing could occur in 2018.

TG-1101 in Combination with TGR-1202 Phase 3 Study Program – The UNITY-CLL Trial

In September 2015, we reached an agreement with the FDA regarding an SPA on the design, endpoints and statistical analysis approach of a Phase 3 clinical trial for the proprietary combination of TG-1101 plus TGR-1202, for the treatment of CLL. The SPA provides agreement that the Phase 3 trial design adequately addresses objectives that, if met, would support the regulatory submission for drug approval of both TG-1101 and TGR-1202 in combination.

The Phase 3 trial, called the UNITY-CLL trial, is a randomized controlled clinical trial that includes two key objectives: first, to demonstrate contribution of each agent in the TG-1101 + TGR-1202 regimen (the combination sometimes referred to as "U2"), and second, to demonstrate superiority in Progression Free Survival (PFS) over the standard of care to support the submission for full approval of the combination. The study will randomize patients into four treatment arms: TG-1101 + TGR-1202, TG-1101 alone, TGR-1202 alone, and an active control arm of obinutuzumab (GAZYVA®) + chlorambucil. An early interim analysis will assess contribution of each single agent in the TG-1101 + TGR-1202 combination regimen, which, if successful, will allow early termination of both single agent arms. A second interim analysis will be conducted following full enrollment into the study, which, if positive, we plan to utilize for accelerated approval.

In September 2017, we announced that target enrollment in the UNITY-CLL trial was met and that we were extending enrollment until October 2017 for any additional identified study patients to be allowed in the trial. We expect top-line ORR data from this study to be reported in 2018.

TG-1101 in Combination with TGR-1202 with or without bendamustine Phase 2b Registration-Directed Program – The UNITY-NHL Trial

In June 2016, we commenced a registration-directed UNITY-DLBCL Phase 2b clinical study evaluating TG-1101 in combination with TGR-1202, as well as TGR-1202 alone, in patients with previously treated DLBCL. In mid-2017, this study was expanded to allow enrollment of patients with follicular lymphoma (FL), small lymphocytic lymphoma (SLL), mantle cell lymphoma (MCL) and marginal zone lymphoma (MZL), as well as to add a cohort evaluating the triplet regimen of TG-1101 + TGR-1202 + bendamustine which has previously been explored in Phase 1. The cohorts of DLBCL, FL/SLL, MCL, and MZL are each being enrolled to and evaluated independently.

The updated study, called UNITY-NHL, is entitled "A Phase 2b Randomized Study to Assess the Efficacy and Safety of the Combination of Ublituximab + TGR-1202 with or without bendamustine and TGR-1202 alone in Patients with Previously Treated Non-Hodgkin's Lymphoma." The DLBCL component is being led by Owen A. O'Connor, MD, PhD, Professor of Medicine and Experimental Therapeutics, and Director of the Center for Lymphoid Malignancies at Columbia University Medical Center, while the indolent NHL component of the study is being led by Nathan H. Fowler, MD, Associate Professor, Department of Lymphoma/Myeloma at the University of Texas MD Anderson Cancer Center, and the MCL component of the study is being led by Michael Wang MD, Director of Mantle Cell Lymphoma (MCL) Program of Excellence and Co-Director of Clinical Trials at The University of Texas MD Anderson Cancer Center. The primary objective of the study is to assess the efficacy of TGR-1202 alone, in combination with TG-1101, or in combination with TG-1101 and bendamustine in patients with previously treated NHL as measured by Overall Response Rate (ORR). The study will also provide important information as to the contribution of each agent, TGR-1202 and TG-1101, to the combination regimen of both agents, as well as the contribution of bendamustine to the combination regimen of both agents.

Single Agent TG-1101 in Relapsing Forms of Multiple Sclerosis

In May 2016, we commenced our first study of TG-1101 in patients with relapsing remitting multiple sclerosis (RRMS), a chronic demyelinating disease of the central nervous system (CNS).

The study, entitled "A Placebo-Controlled Multi-Center Phase 2 Dose Finding Study of Ublituximab, a Third-Generation Anti-CD20 Monoclonal Antibody, in Patients with Relapsing Forms of Multiple Sclerosis," is being led by Edward Fox, MD, PhD, Director of the Multiple Sclerosis Clinic of Central Texas and Clinical Assistant Professor at the University of Texas Medical Branch in Round Rock, TX. The primary objective of the study is to determine the optimal dosing regimen for TG-1101 with a focus on accelerating infusion times. In addition to monitoring for safety and tolerability at each dosing cohort, B-cell depletion and established MS efficacy endpoints

will also be evaluated.

Data from this study was most recently presented at the 4th Congress of the European Academy of Neurology (EAN) in Lisbon, Portugal and at the American Academy of Neurology (AAN) 70th Annual Meeting in Los Angeles, California. Additional data presentations are to be expected at upcoming medical conferences.

TG-1101 in relapsing forms of Multiple Sclerosis Phase 3 Study Program – The ULTIMATE I and ULTIMATE II Trial

In August 2017, we reached an agreement with the FDA regarding an SPA on the design of two Phase 3 clinical trials for TG-1101, for the treatment of relapsing forms of Multiple Sclerosis (RMS). The SPA provides agreement that the two Phase 3 trial designs adequately address objectives that, if met, would support the regulatory submission for approval of TG-1101.

The RMS Phase 3 program consists of two trials, called the ULTIMATE I and ULTIMATE II trials. Each trial is a global, randomized, multi-center, double-blinded, double-dummy, active-controlled study comparing TG-1101 (ublituximab) to teriflunomide in subjects with RMS. The primary endpoint for each study is Annualized Relapse Rate (ARR) following 96 weeks of treatment. Each trial is ongoing and was designed to enroll approximately 440 subjects, randomized in a 1:1 ratio.

In August 2018, we announced that target enrollment into the ULTIMATE I and II trials has been achieved, and that enrollment would continue into September 2018 to allow identified patients to participate in the study.

TGR-1202

Overview

The phosphoinositide-3-kinases (“PI3Ks”) are a family of enzymes involved in various cellular functions, including cell proliferation and survival, cell differentiation, intracellular trafficking, and immunity. There are four isoforms of PI3K (alpha, beta, delta, and gamma), of which the delta isoform is strongly expressed in cells of hematopoietic origin, and often implicated in B-cell related lymphomas.

TGR-1202 (also referred to as umbralisib) is an orally available PI3K delta inhibitor with nanomolar potency to the delta isoform and high selectivity over the alpha, beta, and gamma isoforms. TGR-1202 has demonstrated activity in several pre-clinical models and primary cells from patients with hematologic malignancies.

We hold exclusive worldwide rights to develop and commercialize TGR-1202 for all indications worldwide, except for India which has been retained by Rhizen Pharmaceuticals S A.

The Company’s Investigational New Drug (“IND”) application for TGR-1202 was accepted by the FDA in December 2012 and a first in-human Phase I clinical trial was initiated in January 2013.

Clinical Trials Overview and Recent Developments

Initial clinical development of TGR-1202 was focused on establishing preliminary safety and efficacy in a wide variety of hematologic malignancies. Upon identification of safe and active doses of TGR-1202, a combination clinical trial program was opened, exploring TGR-1202 in combination with a variety of agents. In addition to the previously described study in combination with TG-1101 with or without the BTK inhibitor, ibrutinib, our current priority clinical trials for TGR-1202 include:

TGR-1202 as a single agent in CLL patients who are intolerant to prior BTK inhibitor or PI3K-delta inhibitor therapy;

TGR-1202 in combination with the BTK inhibitor, ibrutinib, in patients with previously treated CLL and MCL; and

TGR-1202 in combination with the JAK inhibitor, ruxolitinib (JAKAFI®), in patients with previously treated Myelofibrosis or Polycythemia Vera.

Single Agent TGR-1202 in Patients with Relapsed/Refractory Hematologic Malignancies

In January 2013, the Company initiated a Phase I, open label, multi-center, first-in-human clinical trial of TGR-1202 in patients with hematologic malignancies. The study entitled TGR-1202-101, "A Phase I Dose Escalation Study Evaluating the Safety and Efficacy of TGR-1202 in Patients with Relapsed or Refractory Hematologic Malignancies," is being run in collaboration with the Sarah Cannon Research Institute in Nashville, TN with Howard “Skip” Burris, MD, Executive Director, Drug Development as the acting Study Chair. Enrollment is open to patients with relapsed or refractory NHL, CLL, and other select hematologic malignancies. As of February 2016, this study has closed to enrollment

Data from this ongoing Phase I study was published in full in The Lancet Oncology in February 2018, including safety and efficacy information from 90 patients with relapsed or refractory b-cell malignancies, including patients

with CLL and various forms of lymphoma treated with single agent umbralisib.

TGR-1202 Long-term Follow-up Integrated Analysis in Patients with Relapsed/Refractory Hematologic Malignancies

In December 2017, at the 59th American Society of Hematology ("ASH") Annual Meeting, the Company presented integrated data with long term follow-up from 347 patients exposed to TGR-1202 across 5 studies, which continued to demonstrate high response rates in CLL, and FL coupled with a favorable safety profile distinct from other PI3K delta inhibitors.

In June 2018, an update on the data was presented at the 23rd Congress of the European Hematology Association (EHA). The presentation included data pooled from 4 completed or ongoing Phase 1 or 2 studies containing umbralisib, focusing on 177 patients who have been on daily umbralisib for a minimum of 6 months. Patients were heavily pretreated, with 45% of patients having seen 3 or more prior lines of therapy. Umbralisib continued to exhibit a differentiated safety profile compared to prior generation PI3K delta inhibitors. Serious adverse events occurring in >1% of patients after 6 months on therapy were limited to pneumonia (3%), diarrhea (2%), and cellulitis (2%) with only 2% of patients discontinuing umbralisib as a result of diarrhea/colitis after being on umbralisib for more than 6 months.

TGR-1202 TKI Intolerance Study

In June 2018, at the 23rd Congress of the European Hematology Association (EHA), the Company presented data from 47 patients with CLL who were intolerant to prior BTK or PI3K delta inhibitor therapy who were then treated with single agent TGR-1202. TGR-1202 appeared to demonstrate a favorable safety profile in patients intolerant to prior ibrutinib (BTK) or idelalisib (PI3K) with only 13% discontinuing due to an adverse event, of which only one patient discontinued due to a recurrent adverse event (AE) also experienced with prior kinase inhibitor therapy. The median progression free survival (PFS) and overall survival has not been reached with a median follow-up of 9.5 months. Enrollment is now closed with patients continuing to be followed.

TGR-1202 Combination Trials

TGR-1202 is being evaluated in combination with the anti-CD30 antibody drug conjugate, brentuximab vedotin, in patients with relapsed or refractory Hodgkin's lymphoma; in combination with the BTK inhibitor, ibrutinib, in patients with CLL and MCL; and in combination with the JAK inhibitor, ruxolitinib, in patients with Myelofibrosis or Polycythemia Vera. Additional investigator sponsored trials are also underway which are combining TGR-1202 with other approved agents for the treatment of B-cell malignancies.

It is anticipated that updated results from these studies will be presented or updated at future medical conferences.

TGR-1202 in Solid Tumors

In addition to the exploration of TGR-1202 in various hematologic malignancies, a study was opened in October 2015 to evaluate TGR-1202 as a single agent as well as in combination with various chemotherapies for the treatment of select solid tumors. The study, entitled TGR-1202-102, "A Phase I Study Evaluating the Safety and Efficacy of TGR-1202 Alone and in Combination with either nab-paclitaxel + Gemcitabine or with FOLFOX in Patients with Select Relapsed or Refractory Solid Tumors" is being run in collaboration with the Sarah Cannon Research Institute in Nashville, TN with Johanna Bendell, MD, Director of GI Oncology Research as the acting study chair. The study is currently closed to enrollment with patients continuing to be followed for safety and efficacy.

IRAK4

We hold global rights to develop and commercialize the IRAK4 program, which was licensed from Ligand Pharmaceuticals. Our IRAK4 program is currently in pre-clinical development.

PD-L1 and GITR

In March 2015, we entered into a global collaboration agreement for the development and commercialization of anti-PD-L1 and anti-GITR antibody research programs in the field of hematological malignancies. Our anti-PD-L1 recently entered the clinic and our anti-GITR program is currently in pre-clinical development, with pre-clinical data

most recently presented at the American Association for Cancer Research Annual Meeting in March 2017.

In October 2017, we announced that the first patient has been dosed in a Phase 1 clinical trial evaluating the safety and tolerability of our anti-PD-L1 monoclonal antibody, enrolling patients across sites in Australia and New Zealand.

BET

In May 2016, as part of a broader agreement with Jubilant Biosys (“Jubilant”), an India-based biotechnology company, we entered into a sub-license agreement (“JBET Agreement”) with Checkpoint Therapeutics, Inc. (“Checkpoint”), a subsidiary of FBIO, for the development and commercialization of Jubilant’s novel BET inhibitor program in the field of hematological malignancies. The BET inhibitor program is the subject of a family of patents covering compounds that inhibit BRD4, a member of the BET (Bromodomain and Extra Terminal) domain for cancer treatment. Our BET inhibitor program is currently in pre-clinical development.

In April 2018, pre-clinical data for TG-1601, the BET inhibitor, was announced at the American Association for Cancer Research (“AACR”) Annual Meeting in Chicago, IL.

TG-1701: BTK

In January 2018, we entered into a global exclusive license agreement with Jiangsu Hengrui Medicine Co., or Jiangsu (“BTK Agreement”), pursuant to which we obtained worldwide rights, excluding Asia but including Japan, for the development of Hengrui's Bruton's Tyrosine Kinase (“BTK”) inhibitor program, including lead candidate TG-1701 (known in China as SHR-1459), as monotherapy and in combination with TG-1101 and TGR-1202. In addition to TG-1701, the global license agreement covers TG-1702 (SHR-1266), another BTK inhibitor in pre-clinical development. BTK is an essential component of the B-cell receptor signaling pathways that regulate the survival, activation, proliferation, and differentiation of B lymphocytes. Targeting BTK with small molecule inhibitors has been demonstrated to be an effective treatment option for B-cell lymphomas and autoimmune diseases.

In June 2018, pre-clinical data for TG-1701, the BTK inhibitor, was presented at the 23rd Congress of the European Hematology Association in Stockholm, Sweden. TG-1701 is expected to enter the clinic in the second half of 2018.

TG-1801: anti-CD47/anti-CD19

In June 2018, we entered into a Joint Venture and License Option Agreement with Novimmune SA (“Novimmune”) to collaborate on the development and commercialization of Novimmune’s novel first-in-class anti-CD47/anti-CD19 bispecific antibody known as TG-1801 (previously NI-1701). The companies will jointly develop the product on a worldwide basis, focusing on indications in the area of hematologic B-cell malignancies.

GENERAL CORPORATE

Our license revenues currently consist of license fees arising from our agreement with Ildong. We recognize upfront license fee revenues ratably over the estimated period in which we will have certain significant ongoing responsibilities under the sublicense agreement, with unamortized amounts recorded as deferred revenue.

We have not earned any revenues from the commercial sale of any of our drug candidates.

Our research and development expenses consist primarily of expenses related to in-licensing of new product candidates, fees paid to consultants and outside service providers for clinical and laboratory development, facilities-related and other expenses relating to the design, development, manufacture, testing and enhancement of our drug candidates and technologies. We expense our research and development costs as they are incurred.

Our general and administrative expenses consist primarily of salaries and related expenses for executive, finance and other administrative personnel, recruitment expenses, professional fees and other corporate expenses, including investor relations, legal activities and facilities-related expenses.

Our results of operations include non-cash compensation expenses as a result of the grants of stock options and restricted stock. Compensation expense for awards of options and restricted stock granted to employees and directors represents the fair value of the award recorded over the respective vesting periods of the individual awards. The expense is included in the respective categories of expense in the condensed consolidated statements of operations. We expect to continue to incur significant non-cash compensation expenses.

For awards of options and restricted stock to consultants and other third-parties, compensation expense is determined at the “measurement date.” The expense is recognized over the vesting period of the award. Until the measurement date is reached, the total amount of compensation expense remains uncertain. We record compensation expense based on the fair value of the award at the reporting date. The awards to consultants and other third-parties are then revalued, or the total compensation is recalculated based on the then current fair value, at each subsequent reporting date. This results in a change to the amount previously recorded in respect of the equity award grant, and additional expense or a

reversal of expense may be recorded in subsequent periods based on changes in the assumptions used to calculate fair value, such as changes in market price, until the measurement date is reached and the compensation expense is finalized.

In addition, certain restricted stock issued to employees vest upon the achievement of certain milestones; therefore, the total expense is uncertain until the milestone is probable.

Our clinical trials will be lengthy and expensive. Even if these trials show that our drug candidates are effective in treating certain indications, there is no guarantee that we will be able to record commercial sales of any of our drug candidates in the near future. In addition, we expect losses to continue as we fund in-licensing and development of new drug candidates. As we further our development efforts, we may enter into additional third-party collaborative agreements and incur additional expenses, such as licensing fees and milestone payments. In addition, we may need to establish a commercial infrastructure required to manufacture, market and sell our drug candidates following approval, if any, by the FDA or a foreign health authority, which would result in incurring additional expenses. As a result, our quarterly results may fluctuate and a quarter-by-quarter comparison of our operating results may not be a meaningful indication of our future performance.

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RESULTS OF OPERATIONS

Three months ended June 30, 2018 and 2017

License Revenue. License revenue was approximately \$38,000 for each of the three months ended June 30, 2018 and 2017. License revenue is related to the amortization of an upfront payment of \$2.0 million received in 2012 associated with our license agreement with Ildong. The upfront payment from Ildong will be recognized as license revenue on a straight-line basis through December 2025, which represents the estimated period over which the Company will have certain ongoing responsibilities under the sublicense agreement.

Noncash Stock Expense Associated with In-Licensing Agreement (Research and Development). Noncash stock expense associated with in-licensing agreement (research and development) amounted to \$3.0 million for the three months ended June 30, 2018, as compared to zero during the comparable period in 2017. The expense during the three months ended June 30, 2018 was recorded in conjunction with the stock issued to Novimmune as an upfront payment for the license to the CD47/CD-19 program.

Noncash Compensation Expense (Research and Development). Noncash compensation expense (research and development) related to equity incentive grants totaled \$0.9 million for the three months ended June 30, 2018, as compared to \$1.3 million during the comparable period in 2017. The decrease in noncash compensation expense was primarily related to a decrease in the measurement date fair value of certain consultant restricted stock during the period ended June 30, 2018.

Other Research and Development Expenses. Other research and development expenses increased by \$9.4 million to \$34.8 million for the three months ended June 30, 2018, as compared to \$25.4 million for the three months ended June 30, 2017. The increase was mainly due to the ongoing clinical development programs and related manufacturing costs for TG-1101 and TGR-1202 during the three months ended June 30, 2018. We expect our other research and

development costs to remain relatively consistent for the remainder of 2018 as we complete enrollment in our registration directed clinical trials and we prepare for potential commercialization.

Noncash Compensation Expense (General and Administrative). Noncash compensation expense (general and administrative) related to equity incentive grants increased by \$3.2 million to \$3.4 million for the three months ended June 30, 2018, as compared to \$0.2 million for the three months ended June 30, 2017. The increase in noncash compensation expense was primarily related to greater compensation expense during the three months ended June 30, 2018 related to restricted stock granted to executive personnel.

Other General and Administrative Expenses. Other general and administrative expenses increased by \$0.8 million to \$2.3 million for the three months ended June 30, 2018, as compared to \$1.5 million for the three months ended June 30, 2017. The increase was due primarily to rent related expenses of our office space, as well as increased personnel and other general and administrative costs. We expect our other general and administrative expenses to remain at a comparable level for the remainder of 2018.

Other (Income) Expense. Other income increased by approximately \$0.1 million to approximately \$0.2 million for the three months ended June 30, 2018, as compared to approximately \$70,000 for the three months ended June 30, 2017. The increase is mainly due to an increase in interest income for the three months ended June 30, 2018.

Six months ended June 30, 2018 and 2017

License Revenue. License revenue was approximately \$0.1 million for each of the six months ended June 30, 2018 and 2017. License revenue for the six months ended June 30, 2018 and 2017 was related to the amortization of an upfront payment of \$2.0 million received in 2012 associated with our license agreement with Ildong.

Noncash Stock Expense Associated with In-Licensing Agreement (Research and Development). Noncash stock expense associated with in-licensing agreement (research and development) amounted to \$4.0 million for the six months ended June 30, 2018, as compared to zero during the comparable period in 2017. The expense during the six months ended June 30, 2018 was recorded in conjunction with the stock issued to Novimmune and Jiangsu Hengrui as upfront payments for the licenses to the CD47/CD19 and BTK programs, respectively.

Noncash Compensation Expense (Research and Development). Noncash compensation expense (research and development) related to equity incentive grants remained consistent between the two periods totaling \$3.7 million for the six months ended June 30, 2018, as compared to \$3.6 million during the comparable period in 2017.

Other Research and Development Expenses. Other research and development expenses increased by \$20.2 million to \$66.0 million for the six months ended June 30, 2018, as compared to \$45.8 million for the six months ended June 30, 2017. The increase in other research and development expenses was due primarily to new and ongoing clinical development programs and related manufacturing costs for TG-1101 and TGR-1202 during the six months ended June 30, 2018. We expect our other research and development costs to remain relatively consistent for the remainder of 2018 as we complete enrollment in our registration directed clinical trials and we prepare for potential commercialization.

Noncash Compensation Expense (General and Administrative). Noncash compensation expense (general and administrative) related to equity incentive grants increased by \$4.0 million to \$7.9 million for the six months ended June 30, 2018, as compared to \$3.9 million for the six months ended June 30, 2017. The increase in noncash compensation expense was primarily related to greater compensation expense during the six months ended June 30, 2018 related to restricted stock granted to executive personnel.

Other General and Administrative Expenses. Other general and administrative expenses increased by \$1.5 million to \$4.4 million for the six months ended June 30, 2018, as compared to \$2.9 million for the six months ended June 30, 2017. The increase was due primarily to rent related expenses of our new office space, as well as increased personnel and other general and administrative costs. We expect our other general and administrative expenses to remain at a comparable level for the remainder of 2018.

Other (Income) Expense. Other income increased by \$0.2 million to approximately \$0.3 million for the six months ended June 30, 2018, as compared to approximately \$11,000 for the six months ended June 30, 2017. The increase is mainly due to an increase in interest income for the six months ended June 30, 2018.

LIQUIDITY AND CAPITAL RESOURCES

Our primary sources of cash have been from the sale of equity securities, warrant and option exercises, and the upfront payment from our Sublicense Agreement with Ildong. We have not yet commercialized any of our drug candidates and cannot be sure if we will ever be able to do so. Even if we commercialize one or more of our drug candidates, we may not become profitable. Our ability to achieve profitability depends on a number of factors, including our ability to obtain regulatory approval for our drug candidates, successfully complete any post-approval regulatory obligations and successfully commercialize our drug candidates alone or in partnership. We may continue to incur substantial operating losses even if we begin to generate revenues from our drug candidates.

As of June 30, 2018, we had approximately \$126.3 million in cash, cash equivalents, investment securities, and interest receivable. The Company believes its cash, cash equivalents, investment securities, and interest receivable on hand as of June 30, 2018 combined with the additional capital raised in the third quarter of 2018 will be sufficient to fund the Company's planned operations into the fourth quarter of 2019. The actual amount of cash that we will need to operate is subject to many factors, including, but not limited to, the timing, design and conduct of clinical trials for our drug candidates. We are dependent upon significant financing to provide the cash necessary to execute our current operations, including the commercialization of any of our drug candidates.

Cash used in operating activities for the six months ended June 30, 2018 was \$62.2 million as compared to \$49.1 million for the six months ended June 30, 2017. The increase in cash used in operating activities was due primarily to increased expenditures associated with our clinical development programs for TG-1101 and TGR-1202.

For the six months ended June 30, 2018, net cash provided by investing activities was \$7.4 million as compared to \$11.0 million for the six months ended June 30, 2017. The decrease in net cash provided by investing activities was primarily due to greater investment in treasury securities during the six months ended June 30, 2018.

For the six months ended June 30, 2018 and 2017, net cash provided by financing activities of \$104.5 million and \$90.7 million, respectively, related primarily to proceeds from the issuance of common stock as part of our ATM program.

OFF-BALANCE SHEET ARRANGEMENTS

We have not entered into any transactions with unconsolidated entities whereby we have financial guarantees, subordinated retained interests, derivative instruments or other contingent arrangements that expose us to material continuing risks, contingent liabilities, or any other obligations under a variable interest in an unconsolidated entity that provides us with financing, liquidity, market risk or credit risk support.

CRITICAL ACCOUNTING POLICIES

The discussion and analysis of our financial condition and results of operations is based upon our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amount of assets and liabilities and related disclosure of contingent assets and liabilities at the date of our financial statements and the reported amounts of revenues and expenses during the applicable period. Actual results may differ from these estimates under different assumptions or conditions.

We define critical accounting policies as those that are reflective of significant judgments and uncertainties and which may potentially result in materially different results under different assumptions and conditions. In applying these critical accounting policies, our management uses its judgment to determine the appropriate assumptions to be used in making certain estimates. These estimates are subject to an inherent degree of uncertainty. Our critical accounting policies include the following:

Revenue Recognition. We recognize license revenue in accordance with the revenue recognition guidance of ASU No. 2014-09, "Revenue from Contracts with Customers" (Topic 606) ("ASC 606"). We analyze each element of our licensing agreement to determine the appropriate revenue recognition. The terms of the license agreement may include payments to us of non-refundable up-front license fees, milestone payments if specified objectives are achieved, and/or royalties on product sales. We recognize revenue from upfront payments over the period of significant involvement under the related agreements unless the fee is in exchange for a promise to transfer more than one good or service to the customer, in which case we would account for each promised good or service as a performance obligation only if it is (1) distinct or (2) a series of distinct goods or services that are substantially the same and have the same pattern of transfer. For each performance obligation, we would determine whether we satisfy the performance obligation over time by transferring control of a good or service over time. To determine whether our promise is to provide a right to access its intellectual property or a right to use its intellectual property, we would consider the nature of the intellectual property to which the customer will have rights. We have symbolic intellectual property, derived from our association with ongoing activities, including our ordinary business activities. We recognize milestone payments as revenue upon the achievement of specified milestones only if (1) the milestone payment is non-refundable, (2) substantive effort is involved in achieving the milestone, (3) the amount of the milestone is reasonable in relation to the effort expended or the risk associated with achievement of the milestone, and (4) the milestone is at risk for both parties. If any of these conditions are not met, we defer the milestone payment and recognize it as revenue over the estimated period of performance under the contract.

Stock-Based Compensation. We have granted stock options and restricted stock to employees, directors and consultants, as well as warrants to other third parties. For employee and director grants, the value of each option award is estimated on the date of grant using the Black-Scholes option-pricing model. The Black-Scholes model takes into account volatility in the price of our stock, the risk-free interest rate, the estimated life of the option, the closing market price of our stock and the exercise price. We base our estimates of our stock price volatility on the historical volatility of our common stock and our assessment of future volatility; however, these estimates are neither predictive nor indicative of the future performance of our stock. For purposes of the calculation, we assumed that no dividends would be paid during the life of the options and warrants. The estimates utilized in the Black-Scholes calculation involve inherent uncertainties and the application of management judgment. In addition, we are required to estimate

the expected forfeiture rate and only recognize expense for those equity awards expected to vest. As a result, if other assumptions had been used, our recorded stock-based compensation expense could have been materially different from that reported. In addition, because some of the options and warrants issued to employees, consultants and other third-parties vest upon the achievement of certain milestones, the total expense is uncertain.

Total compensation expense for options and restricted stock issued to consultants is determined at the “measurement date.” The expense is recognized over the vesting period for the options and restricted stock. Until the measurement date is reached, the total amount of compensation expense remains uncertain. We record stock-based compensation expense based on the fair value of the equity awards at the reporting date. These equity awards are then revalued, or the total compensation is recalculated based on the then current fair value, at each subsequent reporting date. This results in a change to the amount previously recorded in respect of the equity award grant, and additional expense or a reversal of expense may be recorded in subsequent periods based on changes in the assumptions used to calculate fair value, such as changes in market price, until the measurement date is reached and the compensation expense is finalized.

Accruals for Clinical Research Organization and Clinical Site Costs. We make estimates of costs incurred in relation to external clinical research organizations, or CROs, and clinical site costs. We analyze the progress of clinical trials, including levels of patient enrollment, invoices received and contracted costs when evaluating the adequacy of the amount expensed and the related prepaid asset and accrued liability. Significant judgments and estimates must be made and used in determining the accrued balance and expense in any accounting period. We review and accrue CRO expenses and clinical trial study expenses based on work performed and rely upon estimates of those costs applicable to the stage of completion of a study. Accrued CRO costs are subject to revisions as such trials progress to completion. Revisions are charged to expense in the period in which the facts that give rise to the revision become known. With respect to clinical site costs, the financial terms of these agreements are subject to negotiation and vary from contract to contract. Payments under these contracts may be uneven, and depend on factors such as the achievement of certain events, the successful recruitment of patients, the completion of portions of the clinical trial or similar conditions. The objective of our policy is to match the recording of expenses in our financial statements to the actual services received and efforts expended. As such, expense accruals related to clinical site costs are recognized based on our estimate of the degree of completion of the event or events specified in the specific clinical study or trial contract.

We are required to perform impairment tests annually, at December 31, and whenever events or changes in circumstances suggest that the carrying value of an asset may not be recoverable. For all of our acquisitions, various analyses, assumptions and estimates were made at the time of each acquisition that were used to determine the valuation of goodwill and intangibles. In future years, the possibility exists that changes in forecasts and estimates from those used at the acquisition date could result in impairment indicators.

Accounting For Income Taxes. In preparing our condensed consolidated financial statements, we are required to estimate our income taxes in each of the jurisdictions in which we operate. This process involves management estimation of our actual current tax exposure and assessment of temporary differences resulting from differing treatment of items for tax and accounting purposes. These differences result in deferred tax assets and liabilities. We must then assess the likelihood that our deferred tax assets will be recovered from future taxable income and, to the extent we believe that recovery is not likely, we must establish a valuation allowance. To the extent we establish a valuation allowance or increase this allowance in a period, we must include an expense within the tax provision in the consolidated statements of operations. Significant management judgment is required in determining our provision for income taxes, our deferred tax assets and liabilities and any valuation allowance recorded against our net deferred tax assets. We have fully offset our deferred tax assets with a valuation allowance. Our lack of earnings history and the uncertainty surrounding our ability to generate taxable income prior to the reversal or expiration of such deferred tax assets were the primary factors considered by management in maintaining the valuation allowance.

Fair Value of 5% Notes Payable. We measure certain financial assets and liabilities at fair value on a recurring basis in the financial statements. The hierarchy ranks the quality and reliability of inputs, or assumptions, used in the determination of fair value and requires financial assets and liabilities carried at fair value to be classified and disclosed in one of three categories.

We elected the fair value option for valuing the 5% Notes. We elected the fair value option in order to reflect in our financial statements the assumptions that market participants use in evaluating these financial instruments.

RECENTLY ISSUED ACCOUNTING STANDARDS

In July 2018, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2018-11, "Leases - Targeted Improvements" ("ASU 2018-11") as an update to ASU 2016-02, Leases ("ASU 2016-02" or "Topic 842") issued on February 25, 2016. ASU 2016-02 is effective for public business entities for fiscal years beginning January 1, 2019. ASU 2016-02 required companies to adopt the new leases standard at the beginning of the earliest period presented in the financial statements, which is January 1, 2017, using a modified retrospective transition method where lessees must recognize lease assets and liabilities for all leases even though those leases may have expired before the effective date of January 1, 2017. Lessees must also provide the new and enhanced disclosures for each period presented, including the comparative periods.

ASU 2018-11 provides an entity with an additional (and optional) transition method to adopt the new leases standard. Under this new transition method, an entity initially applies the new leases standard at the adoption date and recognizes a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. Consequently, an entity's reporting for the comparative periods presented in the financial statements in which it adopts the new leases standard will continue to be in accordance with current GAAP (Topic 840, Leases). An entity that elects this additional (and optional) transition method must provide the required Topic 840 disclosures for all periods that continue to be in accordance with Topic 840. The amendments do not change the existing disclosure requirements in Topic 840. An entity shall apply the effects of modification using one of the following two methods:

Retrospectively to each prior reporting period presented in the financial statements with the cumulative effect of initially applying ASU 2018-11 recognized at the beginning of the earliest comparative period presented. Under this transition method, the application date shall be the later of the beginning of the earliest period presented in the financial statements and the commencement date of the lease.

Retrospectively at the beginning of the period of adoption through a cumulative-effect adjustment. Under this transition method, the application date shall be the beginning of the reporting period in which the entity first applies ASU 2018-11.

ASU 2018-11 is effective for public business entities for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years, with earlier adoption permitted. We are currently evaluating the impact the adoption of ASU 2018-11 will have on our consolidated financial statements.

In June 2018, the FASB issued ASU No. 2018-07, "Improvements to Nonemployee Share-Based Payment Accounting" ("ASU 2018-07"). ASU 2018-07 expands the scope of FASB Topic 718, Compensation – Stock Compensation ("Topic 718") to include share-based payment transactions for acquiring goods and services from nonemployees. An entity should only remeasure equity-classified awards for which a measurement date has not been established through a cumulative-effect adjustment to retained earnings as of the beginning of the fiscal year of adoption. Upon transition, the entity is required to measure these nonemployee awards at fair value as of the adoption date. The entity must not remeasure assets that are completed. Disclosures required at transition include the nature of and reason for the change in accounting principle and, if applicable, quantitative information about the cumulative effect of the change on retained earnings or other components of equity.

ASU 2018-07 is effective for public business entities for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. Early adoption is permitted, but no earlier than an entity's adoption date of Topic 606. We are currently evaluating the impact the adoption of ASU 2018-07 will have on our consolidated financial statements.

In May 2017, the FASB issued ASU No. 2017-09, “Scope of Modification Accounting” (“ASU 2017-09”). ASU 2017-09 provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting. An entity should account for the effects of a modification unless all the following are met:

The fair value (or calculated value or intrinsic value, if such an alternative measurement method is used) of the modified award is the same as the fair value (or calculated value or intrinsic value, if such an alternative measurement method is used) of the original award immediately before the original award is modified. If the modification does not affect any of the inputs to the valuation technique that the entity uses to value the award, the entity is not required to estimate the value immediately before and after the modification.

The vesting conditions of the modified award are the same as the vesting conditions of the original award immediately before the original award is modified.

The classification of the modified award as an equity instrument or a liability instrument is the same as the classification of the original award immediately before the original award is modified.

ASU 2017-09 is effective for annual and interim periods beginning on or after December 15, 2017. Early adoption is permitted for public business entities for reporting periods for which financial statements have not yet been issued, and all other entities for reporting periods for which financial statements have not yet been made available for issuance. The amendments should be applied prospectively to an award modified on or after the adoption date. The Company adopted ASU 2017-09 on January 1, 2018. The adoption of ASU 2017-09 did not have a material effect on our consolidated financial statements as of June 30, 2018.

In January 2017, the FASB issued ASU No. 2017-04, “Simplifying the Test for Goodwill Impairment” (“ASU 2017-04”). ASU 2017-04 removes the requirement to compare the implied fair value of goodwill with its carrying amount as part of step 2 of the goodwill impairment test. As a result, under ASU 2017-04, an entity should perform its annual, or interim, goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount and should recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit’s fair value; however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. In addition, ASU 2017-04:

Clarifies the requirements for excluding and allocating foreign currency translation adjustments to reporting units in connection with an entity’s testing of reporting units for goodwill impairment.

Clarifies that an entity should consider income tax effects from any tax deductible goodwill on the carrying amount of the reporting unit when measuring the goodwill impairment loss, if applicable.

Makes minor changes to the overview and background sections of certain ASC subtopics and topics as part of the Board’s initiative to unify and improve those sections throughout the Codification.

ASU 2017-04 is effective prospectively for annual and interim periods beginning on or after December 15, 2019, and early adoption is permitted on testing dates after January 1, 2017. The Company does not expect the adoption of ASU 2017-04 to have a material impact on the Company’s condensed consolidated financial statements.

In January 2017, the FASB issued ASU No. 2017-01, “FASB Clarifies the Definition of a Business” (“ASU 2017-01”). ASU 2017-01 clarifies the definition of a business in ASC 805. The amendments in ASU 2017-01 are intended to make application of the guidance more consistent and cost-efficient. The amendments in ASU 2017-01:

Provide a screen to determine when a set of assets and activities is not a business. The screen requires that when substantially all of the fair value of the gross assets acquired (or disposed of) is concentrated in a single identifiable asset or a group of similar identifiable assets, the set is not a business. This screen reduces the number of transactions that need to be further evaluated.

Provide that if the screen is not met, (1) to be considered a business, a set must include, at a minimum, an input and a substantive process that together significantly contribute to the ability to create output and (2) remove the evaluation of whether a market participant could replace missing elements. The amendments provide a framework to assist entities in evaluating whether both an input and a substantive process are present. The framework includes two sets of criteria to consider that depend on whether a set has outputs. Although outputs are not required for a set to be a business, outputs generally are a key element of a business; therefore, the Board has developed more stringent criteria for sets without outputs.

Narrow the definition of the term output so that the term is consistent with how outputs are described in Topic 606.

ASU 2017-01 is effective for annual and interim periods beginning after December 15, 2017, with early adoption permitted for transactions that occurred before the issuance date or effective date of the standard if the transactions were not reported in financial statements that have been issued or made available for issuance. The Company adopted ASU 2017-01 on January 1, 2018. The adoption of ASU 2017-01 did not have a material effect on our consolidated financial statements as of June 30, 2018.

In November 2016, the FASB issued ASU No. 2016-18, “Statement of Cash Flows – Restricted Cash” (“ASU 2016-18”). ASU 2016-18 requires that a statement of cash flows explain the change during the period for the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. ASU 2016-18 does not provide a definition of restricted cash or restricted cash equivalents, and does not change the balance sheet presentation for such items. The Company adopted ASU 2016-18 on January 1, 2018. The adoption of ASU 2016-18 did not have a material effect on our consolidated financial statements as of June 30, 2018.

In May 2014, the FASB issued ASU No. 2014-09, “Revenue from Contracts with Customers” (Topic 606) (“ASU 2014-09” or “ASC 606”), which supersedes all existing revenue recognition requirements, including most industry-specific guidance. ASU 2014-09 provides a single set of criteria for revenue recognition among all industries. The new standard requires a company to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that the Company expects to receive for those goods or services.

ASU 2014-09 includes guidance for determining whether a license transfers to a customer at a point in time or over time based on the nature of the entity's promise to the customer. To determine whether the entity's promise is to provide a right to access its intellectual property or a right to use its intellectual property, the entity should consider the nature of the intellectual property to which the customer will have rights.

ASU 2014-09 is effective for interim and annual periods beginning after December 15, 2017. The standard allows for two transition methods - full retrospective, in which the standard is applied to each prior reporting period presented, or modified retrospective, in which the cumulative effect of initially applying the standard is recognized at the date of initial adoption. The Company adopted ASU 2014-09 on January 1, 2018, using the modified retrospective approach. The adoption of ASU 2014-09 did not have a material effect on our condensed consolidated financial statements as of June 30, 2018.

Other pronouncements issued by the FASB or other authoritative accounting standards with future effective dates are either not applicable or not significant to our consolidated financial statements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The primary objective of our investment activities is to preserve principal while maximizing our income from investments and minimizing our market risk. We invest in government and investment-grade corporate debt in accordance with our investment policy. Some of the securities in which we invest have market risk. This means that a change in prevailing interest rates, and/or credit risk, may cause the fair value of the investment to fluctuate. For example, if we hold a security that was issued with a fixed interest rate at the then-prevailing rate and the prevailing interest rate later rises, the fair value of our investment will probably decline. As of June 30, 2018, our portfolio of financial instruments consists of cash equivalents, including bank deposits, and investments. Due to the short-term nature of our investments, we believe there is no material exposure to interest rate risk, and/or credit risk, arising from our investments.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

As of June 30, 2018, management carried out, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Our disclosure controls and procedures are designed to provide reasonable assurance that information we are required to disclose in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in applicable rules and forms. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of June 30, 2018, our disclosure controls and procedures were effective.

Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended June 30, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We, and our subsidiaries, are not a party to, and our property is not the subject of, any material pending legal proceedings.

ITEM 1A. RISK FACTORS

You should carefully consider the following risks and uncertainties. If any of the following occurs, our business, financial condition or operating results could be materially harmed. These factors could cause the trading price of our common stock to decline, and you could lose all or part of your investment.

Risks Related to Our Business and Industry

Because we have in-licensed our product candidates from third parties, any dispute with or non-performance by our licensors will adversely affect our ability to develop and commercialize the applicable product candidates.

Because we license our intellectual property from third parties and we expect to continue to in-license additional intellectual property rights, if there is any dispute between us and our licensor regarding our rights under a license agreement, our ability to develop and commercialize our product candidates may be adversely affected. Disputes may arise with the third parties from whom we license our intellectual property rights from for a variety of reasons, including:

the scope of rights granted under the license agreement and other interpretation-related issues;

the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the license agreement;

the sublicensing of patent and other rights under our collaborative development relationships and obligations associated with sublicensing;

our diligence obligations under the license agreement and what activities satisfy those diligence obligations;

the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and

the priority of invention of patented technology.

In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations, or may conflict in such a way that puts us in breach of one or more agreements, which would make us susceptible to lengthy and expensive disputes with one or more of our licensing partners. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

We do not have full internal development capabilities, and are thus reliant upon our partners and third parties to generate clinical, preclinical and quality data necessary to support the regulatory applications needed to conduct clinical trials and file for marketing approval.

In order to submit and maintain an Investigational New Drug application (“IND”), Biologics License Application (“BLA”), or New Drug Application (“NDA”) to the United States Food and Drug Administration (“FDA”), it is necessary to submit all information on the clinical, non-clinical, chemistry, manufacturing, controls and quality aspects of the product candidate. We rely on our third party contractors and our licensing partners to provide a significant portion of this data. If we are unable to obtain this data, or the data is not sufficient to meet the regulatory requirements, we may experience significant delays in our development programs. Additionally, an IND must be active in each division in

which we intend to conduct clinical trials. Currently we do not have an active IND for any of the IRAK4, BTK, or BET inhibitors, nor for our anti-GITR or anti-CD47/ anti-CD-19 antibodies. Additionally, there can be no assurance given that any of the molecules under development in our IRAK4, BTK, or BET inhibitor program or in our anti-GITR or anti-CD47/ anti-CD-19 antibody research programs will demonstrate sufficient pharmacologic properties during pre-clinical evaluation to advance to IND enabling studies, or that such IND enabling studies, if any are conducted, will provide data sufficient to support the filing of an IND, or that such IND, if filed, would be accepted by any FDA division under which we would seek to develop any product candidate. While we maintain an active IND for TG-1101 and TGR-1202 enabling the conduct of studies in the FDA's Division of Hematology and Oncology, and an active IND for TG-1101 under the FDA's Division of Neurology, there can be no assurance that we will be successful in obtaining an active IND for these drugs in any other division under whose supervision we may seek to develop our product candidates, or that the FDA will allow us to continue the development of our product candidates in those divisions where we maintain an active IND.

We are highly dependent on the success of our product candidates and cannot give any assurance that these or any future product candidates will be successfully commercialized.

We are a development-stage biopharmaceutical company, and do not currently have any commercial products that generate revenues or any other sources of revenue. We may never be able to successfully develop marketable products. Our pharmaceutical development methods are unproven and may not lead to commercially viable products for any of several reasons.

If we are unable to develop, or receive regulatory approval for or successfully commercialize any of our product candidates, we will not be able to generate product revenues. Even if we are able to develop or receive regulatory approval for or successfully commercialize any of our product candidates, we may not be able to gain market acceptance for our product candidates and future products and may never become profitable.

Because the results of preclinical studies and early clinical trials are not necessarily predictive of future results, any product candidate we advance into clinical trials may not have favorable results in later clinical trials, if any, or receive regulatory approval.

Pharmaceutical development has inherent risk. We will be required to demonstrate through adequate and well-controlled clinical trials that our product candidates are effective with a favorable benefit-risk profile for use in diverse populations for their target indications before we can seek regulatory approvals for their commercial sale. Success in early clinical trials does not mean that later clinical trials will be successful because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety or efficacy despite having progressed through initial clinical testing. Companies frequently suffer significant setbacks in advanced clinical trials, even after earlier clinical trials have shown promising results. In addition, there is typically an extremely high rate of failure of pharmaceutical candidates proceeding through clinical trials.

We plan on conducting additional Phase I, II and III clinical trials for TG-1101 and TGR-1202. Early clinical results seen with TG-1101 and TGR-1202 in a small number of patients may not be reproduced in expanded or larger clinical trials. Additionally, individually reported outcomes of patients treated in clinical trials may not be representative of the entire population of treated patients in such studies. Further, larger scale Phase III studies, which are often conducted internationally, are inherently subject to increased operational risks compared to earlier stage studies, including the risk that the results could vary on a region to region, or country to country basis which could materially adversely affect the study's outcome or the opinion of the validity of the study results by applicable regulatory agencies. Early clinical trial results from interim analysis or from the review of a Data Safety Monitoring Board ("DSMB") or similar safety committee may not be reflective of the results of the entire study, when completed. Additionally, many of the results reported in our early clinical trials rely on local investigator assessed safety and efficacy outcomes which may differ from results assessed in a blinded, independent, centrally reviewed manner, often required of adequate and well controlled registration directed clinical trials which may be undertaken at a later date. If the results from expansion cohorts or later trials are different from those found in the earlier studies of TG-1101 and TGR-1202, we may need to terminate or revise our clinical development plan, which could extend the time for conducting our development program and could have a material adverse effect on our business. Our IRAK4, BTK, BET, anti-CD47/ anti-CD-19, and anti-GITR programs are all in pre-clinical development and no assurance can be given that they will advance into clinical development. If the results from additional pre-clinical studies or early clinical trials differ from those found in earlier studies, our clinical development plans and timelines for this program could be adversely affected which could have a material adverse effect on our business. Many drugs fail in the early stages of clinical development for safety and tolerability issues and accordingly if our pre-clinical assets advance into clinical development, no assurance can be made that a safe and efficacious dose can be found.

If we are unable to successfully complete our clinical trial programs, or if such clinical trials take longer to complete than we project, our ability to execute our current business strategy will be adversely affected.

Whether or not and how quickly we complete clinical trials is dependent in part upon the rate at which we are able to engage clinical trial sites and, thereafter, the rate of enrollment of patients, and the rate we collect, clean, lock and analyze the clinical trial database. Patient enrollment is a function of many factors, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the study, the existence of competitive clinical trials, and whether existing or new drugs are approved for the indication we are studying. We are aware that other companies are currently conducting or planning clinical trials that seek to enroll patients with the same diseases that we are studying. Certain clinical trials are designed to continue until a pre-determined number of events have occurred in the patients enrolled. Trials such as this are subject to delays stemming from patient withdrawal and from lower than expected event rates. They may also incur additional costs if enrollment is increased in order to achieve the desired number of events. If we experience delays in identifying and contracting with sites and/or in patient enrollment in our clinical trial programs, we may incur additional costs and delays in our development programs, and may not be able to complete our clinical trials in a cost-effective or timely manner. In addition, conducting multi-national studies adds another level of complexity and risk. We are subject to events affecting countries outside the United States. Negative or inconclusive results from the clinical trials we conduct or unanticipated adverse medical events could cause us to have to repeat or terminate the clinical trials.

In September 2015 we announced a Phase 3 clinical trial for the combination of TG-1101 + TGR-1202 for patients with Chronic Lymphocytic Leukemia (“CLL”), which is being conducted pursuant to a Special Protocol Assessment (“SPA”) with the FDA and in August 2017 we announced an SPA for our registration program for TG-1101 in relapsing forms of Multiple Sclerosis (“MS”). Many companies which have been granted SPAs and/or the right to utilize the FDA’s Fast Track or accelerated approval process have ultimately failed to obtain final approval to market their drugs. Since we are seeking approvals under SPAs for some of our product registration strategies, based on protocol designs negotiated with the FDA, we may be subject to enhanced scrutiny. Further, any changes or amendments to a protocol that is being conducted under SPA will have to be reviewed and approved by the FDA to verify that the SPA agreement is still valid. Even if the primary endpoint in a Phase 3 clinical trial is achieved, a SPA does not guarantee approval. The FDA may raise issues of safety, study conduct, bias, deviation from the protocol, statistical power, patient completion rates, changes in scientific or medical parameters or internal inconsistencies in the data prior to making its final decision. The FDA may also seek the guidance of an outside advisory committee prior to making its final decision.

The sufficiency of our GENUINE trial results for approval are subject to FDA’s discretion.

Obtaining accelerated approval for an agent requires demonstration of meaningful benefit over available therapies. While we believe we have an understanding of what is considered available therapy today, ultimately the determination of what constitutes available therapy is wholly up to the FDA and is subject to change. In October 2017, we announced the outcome of a meeting with the FDA regarding the use of the results from the GENUINE Phase 3 trial to support a BLA filing for accelerated approval of TG-1101 in combination with ibrutinib. As part of the discussion, the FDA also guided that if one or more agents obtained full approval before we could obtain accelerated approval, those agents could be considered available therapy, and we would need to show meaningful benefit over those agents as well. No assurance can be given that other agents will not receive full approval prior to our potential receipt of accelerated approval. If that were to occur, no assurance can be given that we would be successful in proving meaningful benefit over those later approved drugs. If we were unable to prove meaningful benefit over any such agents, we would be effectively blocked from receiving accelerated approval.

While we wait to see if any drugs receive full approval and can evaluate the data associated with any such agents, we are continuing to make preparations for a BLA filing for accelerated approval. Whether or not we ultimately file such application will be subject to multiple factors and no assurance can be given that a filing will be made. If a filing is made, the FDA acceptance of such a filing will depend on the FDA’s views on the adequacy of the filing, and further even if the filing is accepted, approval of such a filing is a question wholly within the FDA’s discretion to determine. In addition, if we were to receive accelerated approval, we would be required to conduct a post-market confirmatory study, which we may not complete, or if completed, may prove unsuccessful. In such instance, the FDA can remove the product from the market.

The GENUINE study in its final form was not powered for progression-free survival (“PFS”). There can be no assurance given that we will reach agreement with the FDA on an acceptable use of PFS data from GENUINE to support approval of TG-1101, or even if an agreement is reached, that the PFS results of TG-1101 will be positive and/or sufficient to support a regulatory approval of TG-1101.

Any product candidates we may advance through clinical development are subject to extensive regulation, which can be costly and time consuming, cause unanticipated delays or prevent the receipt of the required approvals or “fast track” or “priority review” status to commercialize our product candidates.

The clinical development, manufacturing, labeling, storage, record-keeping, advertising, promotion, import, export, marketing and distribution of our product candidates or any future product candidates are subject to extensive regulation by the FDA in the United States and by comparable health authorities worldwide. In the United States, we

are not permitted to market our product candidates until we receive approval of a BLA or NDA from the FDA. The process of obtaining BLA and NDA approval is expensive, often takes many years and can vary substantially based upon the type, complexity and novelty of the products involved. Approval policies or regulations may change and the FDA has substantial discretion in the pharmaceutical approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. Even with “fast track” or “priority review” status which we intend to seek for our product candidates, where possible, including with regard to TG-1101, such designations do not necessarily mean a faster development process or regulatory review process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures. In addition, the FDA may require post-approval clinical trials or studies which also may be costly. The FDA approval for a limited indication or approval with required warning language, such as a boxed warning, could significantly impact our ability to successfully market our product candidates. Finally, the FDA may require adoption of a Risk Evaluation and Mitigation Strategy (“REMS”) requiring prescriber training, post-market registries, or otherwise restricting the marketing and dissemination of these products. Despite the time and expense invested in clinical development of product candidates, regulatory approval is never guaranteed. Assuming successful clinical development, we intend to seek product approvals in countries outside the United States. As a result, we would be subject to regulation by the European Medicines Agency (“EMA”), as well as the other regulatory agencies in these countries.

Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. As in the United States, the regulatory approval process in Europe and in other countries is a lengthy and challenging process. The FDA, and any other regulatory body around the world can delay, limit or deny approval of a product candidate for many reasons, including:

the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;

we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for any indication;

the FDA may not accept clinical data from trials which are conducted by individual investigators or in countries where the standard of care is potentially different from the United States;

the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;

we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;

the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;

the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a BLA, NDA or other submission or to obtain regulatory approval in the United States or elsewhere;

the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we or our collaborators contract for clinical and commercial supplies; or

the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

In addition, raising questions about the safety of marketed pharmaceuticals may result in increased cautiousness by the FDA and other regulatory authorities in reviewing new pharmaceuticals based on safety, efficacy or other regulatory considerations and may result in significant delays in obtaining regulatory approvals. Regulatory approvals for our product candidates may not be obtained without lengthy delays, if at all. Any delay in obtaining, or inability to obtain, applicable regulatory approvals would prevent us from commercializing our product candidates.

Any product candidate we advance into clinical trials may cause unacceptable adverse events or have other properties that may delay or prevent their regulatory approval or commercialization or limit their commercial potential.

Unacceptable adverse events caused by any of our product candidates that we take into clinical trials could cause either us or regulatory authorities to interrupt, delay, modify or halt clinical trials and could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications. This, in turn, could prevent us from commercializing the affected product candidate and generating revenues from its sale.

We have not completed testing of any of our product candidates for the treatment of the indications for which we intend to seek product approval in humans, and we currently do not know the extent that adverse events, if any, will be observed in patients who receive any of our product candidates. To date, clinical trials using TG-1101 and TGR-1202 have demonstrated a toxicity profile that was deemed acceptable by the investigators performing such studies. Such interpretation may not be shared by future investigators or by the FDA and in the case of TG-1101 and TGR-1202, even if deemed acceptable for oncology applications, it may not be acceptable for diseases outside the oncology setting, and likewise for any other product candidates we may develop. Additionally, the severity, duration and incidence of adverse events may increase in larger study populations. With respect to both TG-1101 and TGR-1202, the toxicity when manufactured under different conditions and in different formulations is not known, and it is possible that additional and/or different adverse events may appear upon the human use of those formulations and those adverse events may arise with greater frequency, intensity and duration than in the current formulation. Should we not be able to adequately demonstrate analytical comparability between drug product manufactured under different conditions, the introduction of such new drug product into ongoing trials also has the potential to confound the interpretation of the results or complicate the statistical analysis of such trial. Further, with respect to TGR-1202, although approximately one thousand patients have been dosed amongst all ongoing TGR-1202 studies, the full adverse effect profile of TGR-1202 is not known. It is also unknown as additional patients are exposed for longer durations to TGR-1202, whether greater frequency and/or severity of adverse events are likely to occur. Common toxicities of other drugs in the same class as TGR-1202 include high levels of liver toxicity, infections and colitis, the latter of which notably has presented with later onset, with incidence increasing with duration of exposure. To date, the incidence of these events has been limited for TGR-1202, however no assurance can be given that this safety and tolerability profile will continue to be demonstrated in the future as higher doses, longer durations of exposure, and multiple drug combinations are explored. If any of our product candidates cause unacceptable adverse events in clinical trials, we may not be able to obtain marketing approval and generate revenues from its sale, or even if approved for sale may lack differentiation from competitive products, which could have a material adverse impact on our business and operations.

Additionally, in combination clinical development, there is an inherent risk of drug-drug interactions between combination agents which may affect each component's individual pharmacologic properties and the overall efficacy and safety of the combination regimen. Both TG-1101 and TGR-1202 are being evaluated in combination together, as well as with a variety of other active anti-cancer agents, which may cause unforeseen toxicity, or impact the severity, duration, and incidence of adverse events observed compared to those seen in the single agent studies of these agents. Further, with multi-drug combinations, it is often difficult to interpret or properly assign attribution of an adverse event to any one particular agent, introducing the risk that toxicity caused by a component of a combination regimen could have a material adverse impact on the development of our product candidates. There can be no assurances given that the combination regimens being studied will display tolerability or efficacy suitable to warrant further testing or produce data that is sufficient to obtain marketing approval.

If any of our product candidates receives marketing approval and we, or others, later identify unacceptable adverse events caused by the product, a number of significant negative consequences could result, including:

regulatory authorities may withdraw their approval of the affected product;

regulatory authorities may require a more significant clinical benefit for approval to offset the risk;

regulatory authorities may require the addition of labeling statements that could diminish the usage of the product or otherwise limit the commercial success of the affected product;

we may be required to change the way the product is administered or, conduct additional clinical trials;

we may choose to discontinue sale of the product;

we could be sued and held liable for harm caused to patients;

we may not be able to enter into collaboration agreements on acceptable terms and execute on our business model;
and

our reputation may suffer.

Any one or a combination of these events could prevent us from obtaining or maintaining regulatory approval and achieving or maintaining market acceptance of the affected product or could substantially increase the costs and expenses of commercializing the affected product, which in turn could delay or prevent us from generating any revenues from the sale of the affected product.

We may experience delays in the commencement of our clinical trials or in the receipt of data from preclinical and clinical trials conducted by third parties, which could result in increased costs and delay our ability to pursue regulatory approval.

Delays in the commencement of clinical trials and delays in the receipt of data from preclinical or clinical trials conducted by third parties could significantly impact our product development costs. Before we can initiate clinical trials in the United States for our product candidates, we need to submit the results of preclinical testing, usually in animals, to the FDA as part of an IND, along with other information including information about product chemistry, manufacturing and controls and its proposed clinical trial protocol for our product candidates.

We plan to rely on preclinical and clinical trial data from third parties, if any, for the IND submissions for our product candidates. If receipt of that data is delayed for any reason, including reasons outside of our control, it will delay our

plans for IND filings, and clinical trial plans. This, in turn, will delay our ability to make subsequent regulatory filings and ultimately, to commercialize our products if regulatory approval is obtained. If those third parties do not make this data available to us, we will likely, on our own, have to develop all the necessary preclinical and clinical data which will lead to additional delays and increase the costs of our development of our product candidates.

Before we can test any product candidate in human clinical trials the product candidate enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as in-vitro and animal studies to assess the potential safety and activity of the pharmaceutical product candidate. The conduct of the preclinical tests must comply with federal regulations and requirements including good laboratory practices (“GLP”).

We must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA places the IND on a clinical hold within that 30-day time period. In such a case, we must work with the FDA to resolve any outstanding concerns before the clinical trials can begin. The FDA may also impose clinical holds on a product candidate at any time before or during clinical trials due to safety concerns or non-compliance. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such clinical trial.

The FDA may require that we conduct additional preclinical testing for any product candidate before it allows us to initiate the clinical testing under any IND, which may lead to additional delays and increase the costs of our preclinical development.

Even assuming an active IND for a product candidate, we do not know whether our planned clinical trials for any such product candidate will begin on time, or at all. The commencement of clinical trials can be delayed for a variety of reasons, including delays in:

obtaining regulatory clearance to commence a clinical trial;

identifying, recruiting and training suitable clinical investigators;

reaching agreement on acceptable terms with prospective contract research organizations (“CROs”) and trial sites, the terms of which can be subject to extensive negotiation, may be subject to modification from time to time and may vary significantly among different CROs and trial sites;

obtaining sufficient quantities of a product candidate for use in clinical trials;

obtaining institutional review board (“IRB”) or ethics committee approval to conduct a clinical trial at a prospective site;

identifying, recruiting and enrolling patients to participate in a clinical trial;

retaining patients who have initiated a clinical trial but may withdraw due to adverse events from the therapy, insufficient efficacy, fatigue with the clinical trial process or personal issues; and

unexpected safety findings.

Any delays in the commencement of our clinical trials will delay our ability to pursue regulatory approval for our product candidates. In addition, many of the factors that cause, or lead to, a delay in the commencement of clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate.

Delays in the completion of clinical testing could result in increased costs and delay our ability to generate product revenues.

Once a clinical trial has begun, patient recruitment and enrollment may be slower than we anticipate. Clinical trials may also be delayed as a result of ambiguous or negative interim results. Further, a clinical trial may be suspended or terminated by us, an IRB, an ethics committee or a DSMC overseeing the clinical trial, any of our clinical trial sites with respect to that site or the FDA or other regulatory authorities due to a number of factors, including:

failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;

inspection of the clinical trial operations or clinical trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;

unforeseen safety issues or any determination that the clinical trial presents unacceptable health risks; and

lack of adequate funding to continue the clinical trial.

Changes in regulatory requirements and guidance also may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for re-examination, which may impact the costs, timing and successful completion of a clinical trial. If we experience delays in the completion of, or if we must terminate, any clinical trial of any product candidate that we advance into clinical trials, our ability to obtain regulatory approval for that product candidate will be delayed and the commercial prospects, if any, for the product candidate may be harmed. In addition, many of these factors may also ultimately lead to the denial of regulatory approval of a product candidate. Even if we ultimately commercialize any of our product candidates, other therapies for the same indications may have been introduced to the market during the period we have been delayed and such therapies may have established a competitive advantage over our product candidates.

We intend to rely on third parties to help conduct our planned clinical trials. If these third parties do not meet their deadlines or otherwise conduct the trials as required, we may not be able to obtain regulatory approval for or commercialize our product candidates when expected or at all.

We intend to use CROs to assist in the conduct of our planned clinical trials and will rely upon medical institutions, clinical investigators and contract laboratories to conduct our trials in accordance with our clinical protocols. Our future CROs, investigators and other third parties may play a significant role in the conduct of these trials and the subsequent collection and analysis of data from the clinical trials.

There is no guarantee that any CROs, investigators and other third parties will devote adequate time and resources to our clinical trials or perform as contractually required. If any third parties upon whom we rely for administration and conduct of our clinical trials fail to meet expected deadlines, fail to adhere to its clinical protocols or otherwise perform in a substandard manner, our clinical trials may be extended, delayed or terminated, and we may not be able to commercialize our product candidates.

If any of our clinical trial sites terminate for any reason, we may experience the loss of follow-up information on patients enrolled in our ongoing clinical trials unless we are able to transfer the care of those patients to another qualified clinical trial site. In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, the integrity of the data generated at the applicable clinical trial site may be jeopardized.

As all of our product candidates are still under development, manufacturing and process improvements implemented in the production of those product candidates may affect their ultimate activity or function.

Our product candidates are in the initial stages of development and are currently manufactured in small batches for use in pre-clinical and clinical studies. Process improvements implemented to date have changed, and process improvements in the future may change, the activity profile of the product candidates, which may affect the safety and efficacy of the products. No assurance can be given that the material manufactured from any of the optimized processes will perform comparably to the product candidates as manufactured to date and used in currently available pre-clinical data and or in early clinical trials reported in this or any previous filing. Additionally, future clinical trial results will be subject to the same level of uncertainty if, following such trials, additional process improvements are made. In addition, we have engaged a secondary manufacturer for TG-1101 to meet our current clinical and future commercial needs and anticipate engaging additional manufacturing sources for TGR-1202 to meet expanded clinical trial and commercial needs. While material produced from this secondary manufacturer for TG-1101 has to date demonstrated acceptable comparability to enable introduction into our clinical trials, no assurance can be given that any additional manufacturers will be successful or that material manufactured by the additional manufacturers will perform comparably to TG-1101 or TGR-1202 as manufactured to date and used in currently available pre-clinical data and or in early clinical trials reported in this or any previous filing, or that the relevant regulatory agencies will agree with our interpretation of comparability. If a secondary manufacturer is not successful in replicating the product or experiences delays, or if regulatory authorities impose unforeseen requirements with respect to product comparability from multiple manufacturing sources, we may experience delays in clinical development.

If we fail to adequately understand and comply with the local laws and customs as we expand into new international markets, these operations may incur losses or otherwise adversely affect our business and results of operations.

We expect to operate a portion of our business in certain countries through subsidiaries or through supply and marketing arrangements. In those countries, where we have limited experience in operating subsidiaries and in reviewing equity investees, we will be subject to additional risks related to complying with a wide variety of national and local laws, including restrictions on the import and export of certain intermediates, drugs, technologies and multiple and possibly overlapping tax laws. In addition, we may face competition in certain countries from companies that may have more experience with operations in such countries or with international operations generally. We may also face difficulties integrating new facilities in different countries into our existing operations, as well as integrating employees hired in different countries into our existing corporate culture. If we do not effectively manage our operations in these subsidiaries and review equity investees effectively, or if we fail to manage our alliances, we may lose money in these countries and it may adversely affect our business and results of our operations. In all interactions with foreign regulatory authorities, we are exposed to liability risks under the Foreign Corrupt Practices Act or similar anti-bribery laws.

If our competitors develop treatments for the target indications for which any of our product candidates may be approved, and they are approved more quickly, marketed more effectively or demonstrated to be more effective than our product candidates, our commercial opportunity will be reduced or eliminated.

We operate in a highly competitive segment of the biotechnology and biopharmaceutical market. We face competition from numerous sources, including commercial pharmaceutical and biotechnology enterprises, academic institutions,

government agencies, and private and public research institutions. Many of our competitors have significantly greater financial, product development, manufacturing and marketing resources. Large pharmaceutical companies have extensive experience in clinical testing and obtaining regulatory approval for drugs. Additionally, many universities and private and public research institutes are active in cancer research, some in direct competition with us. We may also compete with these organizations to recruit scientists and clinical development personnel. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

The cancer indications for which we are developing our products have a number of established therapies with which we will compete. Most major pharmaceutical companies and many biotechnology companies are aggressively pursuing new cancer development programs for the treatment of Non-Hodgkin's Lymphoma ("NHL"), CLL, and other B-cell proliferative malignancies, including both therapies with traditional, as well as novel, mechanisms of action. Additionally, numerous established therapies exist for the autoimmune disorders for which we are developing TG-1101, including and in particular, MS.

If approved, we expect TG-1101 to compete directly with Roche Group's Rituxan® (rituximab) and Gazyva® (obinutuzumab or GA-101), and Novartis' Arzerra® (ofatumumab) among others, each of which is currently approved for the treatment of various diseases including NHL and CLL. In addition, a number of pharmaceutical companies are developing antibodies targeting CD20, CD19, and other B-cell associated targets, chimeric antigen receptor T-cell ("CAR-T") immunotherapy, and other B-cell ablative therapy which, if approved, would potentially compete with TG-1101 both in oncology settings as well as in autoimmune disorders. In 2017, the Roche Group's anti-CD20 antibody ocrelizumab was approved